



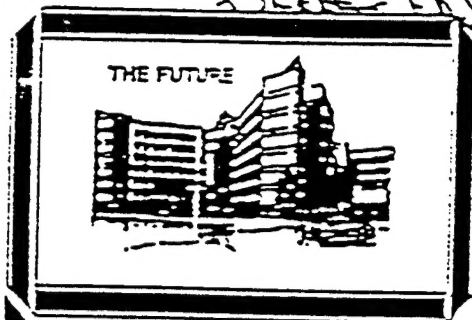
DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1995  
VOLUME I

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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

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13. ABSTRACT (Maximum 200 words) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Use Committee for registration with the Department of Clinical Investigation during Fiscal Year 1995, and known publications and presentations by the Brooke Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach and progress is presented.				
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## FOREWORD

In keeping with tradition, 1995 was another productive year for the Brooke Army Medical Center (BAMC) Department of Clinical Investigation (DCI). The continuing productivity of the DCI is due to the efforts of the DCI staff and to the enthusiastic support of the Commander, BG Robert L. Claypool; the Deputy Commander, COL William D. Strampel; the Chief of Staff, COL Herbert Reamey; and the training program directors.

The philosophy of the DCI is to support and encourage the academic pursuits of the housestaff and professional staff. The goal of the DCI is to assist in developing and fostering research skills in academicians, scientists, and clinicians in the belief that clinical research promotes continuing medical education and ultimately benefits the patient. In keeping with this goal, Drs. Jean Johnson, John Ward, Lawton Seal, Vince Gresham and Jenice Longfield have continued to make presentations on the research process to clinical and administrative services.

The commitment of the medical center to the biomedical research effort is exemplified by the 36% increase in new research projects during FY 95. DCI staff members continue to actively participate in research as well as serve as mentors for young investigators. An energetic nursing research program directed by LTC Linda Yoder of the Department of Nursing successfully competed for grant support for several studies relating to disease and quality of life.

Several MEDCASE and CEEP items were obtained this year which will greatly enhance the basic science and automation capabilities of the DCI. The DCI serves as a resource and support service for investigators in obtaining extramural funding thru establishment of collaborative research with other institutions. Also, to broaden the research teaching program (increased time devoted to), a discussion of ethics in science and medicine will be incorporated in the DCI lectures.

LTC Seal, MAJ Gresham and myself are indebted to the staff of the DCI and BAMC who have supported us during the past year. We are also grateful to those who preceded us and whose efforts contributed to the progress of the past year. We look forward to another year of service to BAMC and the move into the NEW BAMC where state-of-the art instrumentation and technology within the new facility will add to the potential scientific support available to investigators.

*Jenice N. Longfield, MD, MPH*  
JENICE N. LONGFIELD  
Lieutenant Colonel, MC  
Chief, Department of Clinical  
Investigation

\* \* \* \* \*

COMMANDER'S AWARD WINNERS

**First Place**

Protection of the Germinal Epithelium in the Rat  
from the Cytotoxic Effects of Chemotherapy by a Lutenizing  
Hormone Releasing Agonist and Antiandrogen Therapy

R. Duane Cespedes  
Captain, Medical Corps  
Urology Service  
Department of Surgery

**Second Place**

Comparison of Newer Doppler-Echocardiographic Methods  
for the Quantification of Mitral Regurgitation

Jerry Champ  
Major, Medical Corps  
Cardiology Service  
Department of Medicine

**Third Place**

Michael Morris  
Major, Medical Corps  
Pulmonary/Critical Care Service  
Department of Medicine

\* \* \* \* \*

## UNIT SUMMARY

### - FISCAL YEAR 1995

#### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

#### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-3, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

#### C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Longfield, Jenice N.*	LTC	60C9A	Chief
Seal, Lawton A.*	LTC	71A	Microbiologist
Yeager, Curtis**	MAJ	68A	Microbiologist
Eisenhauer, Carol L.**	MAJ	64B	Veterinarian/ Lab Animal Med
Knopp, Gerald L.*	SFC	91K4R	Admin NCO
Look, Beatrice M.**	SSG	92B30	NCOIC
Irizarry, Zulma	SGT	92B20	Med Lab Specialist
Guzman, Edwin	SSG	92B30	Med Lab Specialist
White, James	SGT	92B30	Med Lab Specialist
Hunter, Scott**	SGT	92B30	Med Lab Specialist
Poff, Jennifer	SPC	92B10	Med Lab Specialist
Ruiz, Javier**	SGT	91T20	Animal Care Specialist
Yoquelet, Curtis**	SGT	91T20	Animal Care Specialist
Ortiz, Ruben*	SGT	91T20	Animal Care Specialist
Davis, Reginald*	SGT	91T20	Animal Care Specialist

Barajas, Rene C.*	SFC	91T30	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean M.	GS12	00610	Research Nurse
Reeb, Barbara	GS11	00644	Medical Technologist
Davey, Inid** (salaried by CHAMPUS- assigned to DCI)	GS11	00644	Medical Technologist
Trevino, Sylvia**	GS11	00644	Medical Technologist
Stuart, Sandra*	GS11	00644	Medical Technologist
Chapa, Isidoro	GS09	00645	Medical Technician
Williams, Dannie	GS07	00404	Biological Lab Technician
Rios, Roberto***	GS09	01020	Med Scientific Illustrator
Smith, Helen J.	GS09	00301	Clin Research Protocol Coord
Aguero, Lynda D.	GS06	01087	Editorial Assistant
Johnson, Maurine E.	GS05	00318	Secretary

\* Assigned

\*\* Reassigned

\*\*\* Assigned to IMD with duty in DCI

Personnel:	Authorized	Required	Assigned
Officers -	4	9	3
Civilians -	13	16	12
Enlisted -	7	10	8

#### D. Funding

Type	Fiscal Year 94	Fiscal Year 95
Civilian personnel		
to include benefits	522,776.00	475,895.72
Consumable supplies	152,026.00	156,916.50
Civilian contracts		
to include consultants	4,614.00	11,171.00
TDY	4,279.00	5,000.00
Noninvestment equipment (Minor MEDCASE)	-----	-----
Other OMA	-----	-----
OMA Total	679,081.00	648,983.22
MEDCASE	226,912.00	103,000.00
CEEP	64,290.00	40,376.00
Other (Bone Marrow Unit)	21,898.49	28,875.45
Military	578,000.00	619,000.00
<b>TOTAL</b>	<b>1,574,795.49</b>	<b>1,440,234.67</b>

Grants:

- a. U.S. Army Medical Research and Development Command - \$45,000.00
- b. Southwest Oncology Group - \$226,000.00
- c. Other Nonfederal Gifts - \$122,656.00
- d. NIH - \$133,736.00
- e. CRDA - \$5,000.00

Protocol Disposition FY 95

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 96</u>
FY 77	0	0	0	1
FY 85	0	0	0	0
FY 86	0	0	0	1
FY 87	0	0	2	2
FY 88	0	0	0	4
FY 89	1	0	3	5
FY 90	3	0	13	13
FY 91	2	0	1	29
FY 92	2	0	6	21
FY 93	8	0	20	48
FY 94	13	0	37	108
FY 95	<u>3</u>		<u>8</u>	<u>147</u>
	32		90	379

Animal Research and Training Protocols

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 96</u>
FY 86	0	0	0	0
FY 87	0	0	0	0
FY 88	0	0	0	0
FY 89	0	0	1	0
FY 90	0	0	0	0
FY 91	0	0	0	0
FY 92	1	0	2	1
FY 93	1	0	1	6
FY 94	0	0	4	16
FY 95	<u>0</u>	<u>0</u>	<u>0</u>	<u>6</u>
	2	0	8	29

Oncology Group Protocols

SWOG	4	0	27	128
POG	0	0	5	42

GOG	<u>0</u>	<u>0</u>	<u>0</u>	<u>65</u>
	4	0	32	235

Number of resident and fellowship programs: 23

Number of residents and fellows with approved protocols: 81

Number of approved protocols held by this group: 127

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; Academy of Health Sciences Physical Therapy Branch.

Number of approved protocols held by this group: 43

Number of hospital staff members with approved protocols: 260

Number of approved protocols held by this group: 473

Drug evaluation/comparison studies: 116 (Does not include Oncology Group Protocols)

#### Significant Changes in the Last Year/Changes for the Future

We have become more proactive in recruiting investigators in the MEDCEN.

We have expanded our collaborative efforts with extramural sources. MRMC, the University of Texas Health Science Center at San Antonio and Austin, Cancer Therapy Research Center, and the State Chest Hospital are all collaborators.

#### Changes in Support of Growing Graduate Medical Education Requirements

There is a continuing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development, etc. These requirements are being met by going to the departments and offering tailored instruction for each unit's needs.

We continue to benefit from gifts and grants offered through the Jackson Foundation and organizations such as Facilitators of Applied Clinical Trials (FACT), the National Kidney Foundation and other not for profit organizations. Approvals for gifts of support are being processed in a more expeditious manner due to a better understanding of the approval process.

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#### Publications and Presentations Reported in 1995

Publications: 130

Abstracts: 126

Presentations: 160



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C - Completed  
T - Terminated

**DEPARTMENT OF THE ARMY  
Brooke Army Medical Center  
Fort Sam Houston, TX 78234-6226  
DEPARTMENT OF CLINICAL INVESTIGATION**

**PRESENTATIONS**

**DEPARTMENT OF CLINICAL INVESTIGATION**

Johnson, J: Descriptive and Inferential Statistics. Army Dietetic Interns, Nutrition Care Division, BAMC, Sep 29, Oct 6, 95.

Johnson, J: Institutional Research Review. Mary Lipscomb-Hamrick AMSC-AN Research Conference; San Antonio, TX; 6-7 Aug 95.

Johnson, J: Medication Compliance in Clinical Trials. 7th Annual Tri-Service Clinical Investigation Post Graduate Short Course, New Braunfels, TX, 15 Mar 95.

Johnson, J: Research Utilization Workshop - Phase II of the Process. (Panel presentation with Council of Research Directors and Coordinators, UTHSCSA School of Nursing) for San Antonio Clinical Nurses, 2 Feb 95.

Johnson, J: The Department of Clinical Investigation and Institutional Research Review. Army Nurse Corps Nurse Anesthesia Program - Baylor University; AMEDD Center and School, FSHT, 10 Jan 95.

**DEPARTMENT OF EMERGENCY MEDICINE**

Manthey, D: Ultrasound vs radiographics in soft tissue detection of foreign bodies. Joint Svcs Symposium, San Antonio TX 17 Jan 95. Same at ACEP Research Forum, San Francisco CA 28 Feb 95

Manthey, D: Clinical Case Presentation. Southern Med Assn Regional Mtg, Orlando, FL 5 Nov 94.

Hemphill, R: Pseudosepsis (CPC competition). Southern Regional Med Soc, Orlando, FL Nov 94.

Hemphill, R: Emergency department follow-up in febrile children: A comparison of two systems. Amer Acad of Pediatrics, Dallas TX Oct 94.

Holt, S: LP/CT ACER Rsch Forum, San Francisco, CA, Feb 95.

Holt, S: Pulmonary Function Changes After Deep Saturation Dives. Naval Experimental Dive Unit, FL, Feb 95.

Holt, S: Is LP necessary when using new Generation LT Scanners to exclude subarachnoid hemorrhage? Naval Experimental Dive Unit, FL, Feb 95.

Stack, L: 1. Headaches 2. ER Reading of Head CT Scan 3. Case Studies in

Emerg Med. Loma Linda Univ, Dept Emerg Med Grand Grounds, Mar 95.  
Ackerman, BT: CPC Regional Competition. Soc of Academic Emerg Med, San Antonio,  
19 May 95.

#### DEPARTMENT OF MEDICINE

##### Cardiology Service:

Bulgrin, JR: Comparison of Cohen-class time-frequency distributions of intracardiac heart sounds in man. Asilomar Conf Center, Pacific Grove, CA, 20 Oct-2 Nov 94.

Do, TM; Rubal, BJ; Bulrin, JR; Gilman, JK: Time-fRequency Analysis of ECG for Late Potentials in Sudden Cardiac Death Survivors and Post-Myocardia Infarction Patients. 23rd Annual Rocky Mountain Bioengineering Symposium, 8 Apr 95, Copper Mountain CO.

Bauch, TD; Rubal, BJ; Lecce, MD; Smith, TE; Groch, MW: S2 Triggered Gated Blood Pool Imaging for Assessment of Diastole. 23rd Annual Rocky Mountain Bioengineering Symposium, 9 Apr 95, Copper Mountain CO.

Campos-Esteve, MA: Effect of Clinical Presentation on Outcome of Directional Coronary Atherectomy. The Society of Cardiac Angiography and Interventions, 18 May 95. Hyatt Grand Cypress Hotel in Orlando FL.

Arendt, MA; Rubal, BJ: Acute Effects of Parenteral  $MgSO_4$  on Cardiac Conduction Times and Hemodynamics During Right Atrial Pacing. Experimental Biology 95<sup>TM</sup>, Atlanta GA 9-13 Apr 95.

Rubal, BJ; Bailey, SR: Aortic Stent Implantation Results in Regional Vascular Discontinuity with Changes in Blood Pressure. Society for Cardiac Angiography and Interventions, 18th Annual Mtg, Orlando FL 16-20 May 95.

##### Dermatology Service:

Peake, MK: Diseases of the skin. SOMED SGTs Crs (18 Delta) 11 Oct 94.

Coots, NV: STDs: A primer for High School males. At Project Alpa, Sam Houston H.S., 12 Nov 94.

Peake, MF: Relapsing polychondritis. Presented at the American Academy of Dermatology, New Orleans, LA Feb 95.

Peake MF: Physical examination of the skin. Presented at the Special Operations Medical Branch AMEDD Center and School, Mar 95.

Elston, DM: Office microbiology. Presented at the American Academy of Dermatology, New Orleans LA Feb 95.

Elston, DM: Alopecia and folliculitis. Presented at the Amer Academy of Dermatology, New Orleans LA Feb 95.

#### PRESENTATIONS (continued)

Elston, DM: Lice, mites and arachnoid bites. Microbiology Crs, American Acad of Dermatology, New Orleans, LA Feb 95.

Miller, JJ: Chronic bullous disease of childhood. Presented at the American Acad of Dermatology, New Orleans, LA, Feb 95.

Coots, NV: Mid dermal blastolysis. Presented at the American Academy of Dermatology, New Orleans, LA, Feb 95.

Angeloni, VL: Rickettsia Update. Presented at the American academy of Dermatology Annual Meeting, Feb 95.

Elsto, DM: Bugs and Bites. Presented at Grand Rounds, William Beaumont AMC, El Paso, TX 2 Jun 95.

Peake, MF: Physical Exam of the Skin. Presented to the Special Operations Medical Sergeants Course, May 95.

Keller, RA: Sexually Transmitted Diseases. Guantanamo Bay Medical Conference, Guantanamo Bay, Cuba 7 Feb 95.

Keller, RA: Operations other than War - Operation Sea Signal. AMSUS - 11 Apr 95; Medicine Grand Rounds 18 Apr 95 and Tri-Services Dermatology Seminar 1 May 95.

Coots, NV; Elston, DM: Rorschach Inkblot Portwine Stain. Derm section, National Med Assn Conv, Atlanta, GA, 1 Aug 95.

Coots, NV; Keeling, JK; Becker, LE: Niclosamide, the Schistosome topical Antipenetrant. Military Med Sec, Natl Med Assn Convention, Atlanta, GA, 1 Aug 95.

#### Endocrinology Service:

Thomason, AM: Suppressible thyroglobular values in thyroid cancer. Army ACP, Reston, VA, Oct 94.

Thomason, AM: Triac and Tetrac Appear to Inhibit T Cell Replication In Vitro. Endocrine Soc Mtg, Washington DC 13-17 Jun 95.

#### General Medicine Service:

Marple, R: Re-inventory the doctor's office: Less visits, better care. Army ACP, Reston VA Oct 94.

#### Infectious Disease Service:

McAllister, C: Cellulitis 2° to Grp C Streptococcus City of San Antonio Bug Club, 3 May 95.

## PRESENTATIONS (continued)

Plemmons, R: Pulmonary Paragonamiasis: A Solitary Pul Nodule. City of San Antonio Bug Club

### Pulmonary Disease Service:

Morris, MJ; Peacock, MD; Lloyd, WC: Risk of bleeding in sheep with pulmonary hypertension undergoing transbronchial biopsy. American Col of Chest Physicians Natl Mtg, Nov 94.

Brassard, JM; Johnson, JE; Anders, GT; Blanton, HM: Correlation of APACHE scores with duration of mechanical ventilation in patients with respiratory failure. Amer Col of Chest Physicians Natl Mtg, Nov 94.

Peacock, MD; Houghland, MA; Anders, GT: Incidence of sleep disordered breathing in patients evaluated for gulf war illness. National mtg of the Amer Thoracic Soc, Seattle May 95.

Morris, MJ; Bradley, J; Lee, KY; Roodman, GD; Jenkinson, SG; Bryan, CL: Changes in serum TGF-B1 in nude mice with chronic TNF-a induced pulmonary fibrosis. National mtg of the Amer Thoracic Soc, Seattle May 95.

### Rheumatology Service:

Grady, EP; Carpenter, MT; Battafarano; Older, SA; Koenig, CD: Rheumatologic Findings in Persian Gulf War Veterans. Amer Col of Rheumatology 95 Natl Sci Mtg, San Francisco CA, 21-26 Oct 95.

## DEPARTMENT OF NURSING

Connelly, LM: A naturalistic study of a nursing orientation program: Implications for staff development. Amer Nurses Assn Council on Continuing Educ and Staff Development Annual Conf, Kansas City, MO 26-29 Oct 94.

Yoder, L: Career Development Relationships for Nurses. Univ of TX at Tyler School of Nursing, Apr 95.

Yoder, L: Making You Work Count. Univ of TX Health Sci Cen at SA School of Nursing PhD Day, Ar 95.

Yoder, L: Making your Work Count. PhD Day, UTHSC Sch of Nursing Apr 95.

Yoder, L: Career Development Relationships for Nurses. UT Tyler Sch of Nursing, 13 Apr 95.

Following lists all who presented at The Regional Research Day sponsored by BAMC 12 May 95:

Connelly, L: A Naturalistic Study of a Nursing Orientation Program.

#### PRESENTATIONS (continued)

Malone, C: Physical Activity or Inactivity Among African Americans in a Rural Community.

Yoder, L; Drady, V: Costs and Outcomes of a Military Bone Marrow Transplant Program.

Reilly, M: Alternative Methods for the Treatment of Pain and Anxiety in the Cataract Patient.

Reineck, C: International/National - Army Nursing Research for the future. European Medical-Surgical Congress, Villengen, Germany.

Yoder, L: Recent Trends in Oncology Nursing. Arkansas State Nurses' Convention.

Yoder, L: Overview of Bone Marrow Transplant. Arkansas State Nurses' Convention.

#### DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Dawley, B: The atypical pap smear. Armed Forces District Mtg of Amer Col of OB-Gyn, Reno NV, Nov 94.

Gehlbach, D: Telemedicine: extending the reach of the Specialist. AFD/ACOG, Reno NV, Nov 94.

Phelps, J: Accuracy and Intraobserver Variability of Cervical Measurement. AFD/ACOG, Reno NV Nov 94.

Whitecar P: Endometrial pathology in breast cancer patients receiving tamoxifen. AFD/ACOG, Reno NV Nov 94.

Thornton, S: Sterilization regret in a military population. AFD/ACOG, Reno NV Nov 94.

Phelps, J: Tuboperitoneal fistula after salpingostomy: A Case Rpt. AFD/ACOG, Reno NV Nov 94/

Gehlback, D: Telemedicine: Extending the reach of the specialist. NCOG Armed Forces District Mtg, Reno, NV 17 Nov 94.

Higby, K; Suiter, CS: A Comparison between two screening methods for the detection of microproteinuria. Joseph Seitchuk Memorial, Univ of TX HSC, 23 Jun 95.

#### DEPARTMENT OF PATHOLOGY

Horton, M: Adenosrcoma of the Uterus. San Antonio Soc of Pathologists, San Antonio, TX, 1 Nov 94.

PRESENTATIONS (continued)

Lerud, KS; Frost, AR; Tabbara, SO; DelVecchio, D: Cytomorphology of Cystic Parathyroid Lesions. Amer Soc of Cytology, Chicago IL 1-6 Nov 94.

Hansa Raval: FNA Biopsy of Breast. Jamnagar Medical College, Tamnagar, India, 20 Sep 94.

Harvey, K: Computer-assisted evaluation of hand function following thermal injury. American Burn Association, Albuquerque, NM, 19-22 Apr 95.

Higby, K: Gestational Diabetes Mellitus. Presented at 15th Annual Society of Parental Obstetricians, Atlanta, GA 23-28 Jan 95.

Higby, K: Preeclampsia and Hypertension. Panamanian Medical Society Meeting, Panama City, Mar 95.

DEPARTMENT OF RADIOLOGY

Chacko, AK: Radiology and telemedicine at Brooke. NIIT Health Care Working Group, kDenver CO 27 Oct 94.

Cawthon, MA: Fifteen months operational experience and update of radiology operations in a PACS environment. Southern Med Assn Mtg, Orlando FL 5 Nov 94.

Deissler, H: Detection of breast abnormalities following digitization of conventional mamographic films. Southern Med Assn Mtg, Orlando FL Nov 94.

Cawthon, MA: Implementation of PACS in new and old facilities: Madigan and Brooke experience. Radiological Soc of North America, Chicago IL Nov 94.

Mogel, G: The effect of compression and soft copy interpretation of neonatal chest x-rays. The European College of Radiology Meeting in Vienna, Austria, 8 Mar 95.

Mogel, G: Soft copy interpretation in emergency radiology. American Society of Emergency Radiologists Meeting in Scotsdale, AZ, Mar 95.

Chacko, AK: Picture Archiving and Communication in DOD. Radiology Centennial Conference, 4-5 May 95, Bethesda, MD.

Chacko, AK: Role of the Radiologist in Telemedicine and the Information Superhighway. Radiology Centennial Conf, 4-5 May 95, Bethesda, MD.

Deisler, H: Detection of Breast Abnormalities Following Digitization of Film-Screen Mammograms. Amer Roentgen Ray Society, 30 Apr-5 May 95, Washington, DC.

Benson, A: Fourth Ventricular Diverticulum in a Patient with Communicating Hydrocephalus and Syringomyelia: MR and CSF Flow Evaluation. Amer Soc of Neuroradiology, Apr 95, Chicago IL.



PRESENTATIONS (continued)

Cawthon, M: Soft Copy Interpretation Implementation Strategies. IMAC 95 Conference In Hawaii, 21-24 Aug 95.

Perez, G: Time Requirements of Hard-versus Soft-Copy Interpretation of SICU Computed Radiographic Images. IMAC 95 Conference In Hawaii, 21-24 Aug 95.

Benson, A; Chacko, AK: The Use of Soft Copy to Enhance the Interpretation of Hard Copy Digital Images. IMAC 95 Conf in Hawaii, 21-24 Aug 95.

DEPARTMENT OF SURGERY

Anesthesiology & Operative Svc:

Thwaites, B, et al: Intravenous Ketorolac Tromethamine does not worsen platelet function during general anesthesia. IARS, Honolulu HI Mar 95.

Thwaites, B: Thromboelastographic evidence of Fibrinolysis strongly predicts excess bleeding after cardiopulmonary bypass. Society of Cardiovascular Anesthesiologists, Philadelphia PA May 95.

Brown, RS; Mongan, PD, Thwaites, BK: Tranxemic acid decreases fibrinolysis, bleeding, and blood transfusions in primary CABG. Anesth Analg 1995;80 supplement. Presented at 1995 Soc of Cardiovascular Anesthesiologists Annual Meeting.

Hecker, RB; Brownfield, RM; Rubal, BJ. Bayesian analysis of non-invasive body temperature methods compared to oral temperature to determine hypothermia in the PACU. Anesth Analg 1995;80:S176. Presented at 1995 International Anes Rsch Soc Annual Meeting.

Fontana, JL; McGlothin, TM; Mongan, PD; Bungere, R: Tachycardia does not reflect profound anemia in a porcine model of normovolemic hemodilution. Anes Analg 1995;80:S131.

McLoughlin, TM; Fontana, JL; Mongan, PD; Bungere, R: Character-ization of the coagulopathy accompanying profound normovolemic hemodilution in swine Anesthesiology 1994;81:S131.

Mongan, PD; Hosking, MP: Desmopressin decreases blood loss and transfusion therapy after high risk CPB procedures. Anes Analg 1994;78:S292.

Thwaites, BK; Mongan, PD; Brown, RS: Thromboelastographic evidence of fibrinolysis strongly predicts excess bleeding after cardiopulmonary bypass. Anesth Analg 1995;80:(in press). Presented at 1995 Society of Cardiovascular Anesthesiologists Annual Meeting.

Thwaites, BK: Intraoperative transesophageal echocardiography. Presented to 1994 US Army Professional Post Graduate Short Course in Anesthesia Nursing.

## PRESENTATIONS (continued)

Presented for Anesthesiology Grand Rounds, Wilford Hall US Air Force Medical Center, San Antonio, TX.

Thwaites, BK: The anatomy and physiology of pain. Presented to US Army Kersey Musculoskeletal Evaluation Crs for Physical Therapists 1993 and 1994.

Thwaites, BK; Nigus, DB; Bouska, G; Mongan, PD. Platelet function during general anesthesia and surgery before and after intravenous ketorolac tromethamine. Anesth Analg 1995;80:S498. Presented at 1995 International Anesthesia Research Society Annual Meeting.

### Cardiothoracic Surgery Service:

Cohen, DJ: Combat Casualty Care: What's New and Battlefield Applicable - Management of Vascular Trauma. Assn of Mil Surgeons of the US, 101st Ann Mtg, Orlando FL 14 Nov 94.

Cohen, DJ: First Annual 1995 Trauma Symposium, OTSG, United States Army, San Antonio, TX, 13-15 Sep 95, "Empyema".

Lisagor, PG: First Annual 1995 Trauma Symposium, OTSG, United States Army, San Antonio, TX 13-15 Sep 95, "Operations Other Than War".

### Neurosurgery Surgery Service:

Alexander, J: Thoracolumbar spine stabilization (Practical Crs). Congress of Neurological Surgeons Annual Meeting, Chicago IL Oct 94.

### Ophthalmology Service:

Sepanski, G; Campagna, J: Medical Management of Glaucoma: A Cost Analysis. Alamo City Clinical Conference, SA TX 3 Mar 95.

Mitchell, K; Campagna, J: The Evaluation of Peripapillary Atrophy and Glaucomatous Optic Nerve Damage Using the Topican Image Analyzer. Alamo City Clinical Conference, SA TX 3 Mar 95.

O'Hara, M: Pediatric Ophthalmology. Ophthalmic Personnel Society of SA, Feb 95, SA TX

O'Hara, M: Strabismus. WBAMC Pediatric Grand Grounds, El Paso, TX Feb 95.

O'Hara, M: Moderator, Pediatric Ophthalmology Section Alamo City Ophthalmology Conference 3 Mar 95, SA TX.

O'Hara, M: Normal & Abnormal Binocular Vision UTHSCSA Ophthalmology Grand Rounds, 10 Mar 95, SA TX.

Bauman, W: Management of Intraocular Foreign Bodies.

PRESENTATIONS (continued)

San Antonio Trauma Symposium, 14 Sep 95.

Campagna, J: IOP & IOP Measuring Devices. Unit of  
TX Health Sci Center at San Antonio Grand Rounds, 14 Jul 95.

Otolaryngology Service:

Ramirez, S: Penetrating neck trauma. 6th Ann Head and Neck Trauma Symposium,  
FSHT 8-9 Dec 94.

Hayes, D: The overall care of the trauma patient. 6th Annual Head and Neck  
Trauma Symposium, FSHT 8-9 Dec 94.

Ramirez, S: Neck Masses. UTHSCSA.

Moss, J: Frontal sinus fracture. 6th Annual Head and Neck Trauma Symposium, FSHT  
8-9 Dec 94.

Staffel, G: Zygoma fractures. 6th Annual Head and Neck Trauma Symposium, FSHT,  
8-9 Dec 94.

Lee, J: Naropharyngeal carcinoma. Grand Rounds, UTHSCSA.

Johnson, R: Temporal bone fracture. UTHSCSA Grand Rounds.

Malis, D: Laryngeal Trauma. UTHSCSA Grand Rounds.

UTHSCSA Grand Rounds, May topics:

McGarrah, P: Auricular Trauma.

Lee, J: Facial Nerve Paresis.

Balbuena, L: Salivary Gland Tumors; and Perioperative Oral Antibiotics.

Sneizek: Laryngoceles.

Johnson, R: Otacoustic Emissions.

Lee, J: Racial Variations in Cephalometric Analysis.

Liening, DA: Otitis and Mastoiditis. Basic Sci  
Crs, Univ of TX Health Sci Cen, Jul 95.

Teller, DC: (1) Zygomatic Fracture. (2) Frontal Sinus Fracture. Basic Sci Crs,  
Univ of TX Health Sci Cen, Jul 95.

Liening, DA: Bio Materials in the Middle Ear. 9th Annual Head & Neck Seminar,  
Madigan AMC, Tacoma WA Aug 95.

PRESENTATIONS (continued)

Bean, DR: Dysphagia. Grand Rounds, Univ of TX Health Sci Cen, Aug 95.

Hayes, DK: Management of Midfacial Fractures. Grand Rounds, Univ of TX Health Sci Cen, Sep 95

Ramirez, SG: Management of Neck Mass. Grand Rounds, Univ of TX Health Sci Cen, Sep 95.

Urology Service:

Thompson IM:

Observation for Localized Prostate Cancer. Crittendon Hospital Symposium on Prostate Cancer, Detroit, MI, 1 Apr 95.

Treatment Options in Prostate Cancer Management. Village Oaks Hospital Board of Directors Mtg, San Antonio, TX 12 Apr 95.

Computer Models and Prostate Cancer. Amer Urol Assn Annual Mtg, Soc of Urologic Oncology Plenary Session Lecture, Las Vegas, NV, 23 Apr 95.

Mortality following Radical Prostatectomy. Amer Urol Assn Ann Mtg, Las Vegas, NV 25 Apr 95.

Postraduate Course Chairman - Complications of Prostate Cancer. Amer Urol Assn Ann Mtg, Las Vegas, NV 6 Apr 95.

Highlights of the Annual Mtg - Prostate Cancer. Amer Urol Assn Ann Mtg, Las Vegas, NV, 28 Apr 95.

Chemoprevention of Prostate Cancer. Ann Charlotte Cancer Symposium, Charlotte, NC 19 May 95.

Chemoprevention of Prostate Cancer. South TX Surgical Soc Ann Mtg, Key West, FL 28 May 95.

The Case for Observation for Localized Prostate Cancer. Chicago Roentgen Society/Chicago Urol Soc - Prostate Cancer Shootout. Chicago, IL 16 Jun 95.

Observation for Prostate Cancer. Northwest Cancer Center Ann Mtg, Seattle, WA 22 Jun 95.

Chemoprevention for Prostate Cancer. Little Rock AFB, Arkansas 29 Jun 95.

Rozanski, TA: The Remnant Orchiectomy. Amer Urol Assn Ann Mtg, Las Vegas, NV Apr 95.

Rozanski, TA: Posterior Urethral Valves. Pediatrics Grand Rounds, BAMC Jun 95.

Rozanski, TA: The Undescended Testis. Theory and Management. Urology Tutorial,

PRESENTATIONS (continued)

BAMC, Jun 95.

Schow, DA: Techniques in Urologic Surgery. Presented semi-annually to OR Nursing staff at BAMC.

Schow, DA: Morbidity and Cancer Control with Radical Perineal Prostatectomy. Amer Urol Assn 19th Ann Mtg Apr 95, Las Vegas NV.

Schow, DA: Radiographic Characteristics of the Vesicourethral Anastomosis Following Radical Perineal and Retropubic Prostatectomy. Amer Urol Assn 19th Ann Mtg Apr 95, Las Vegas, NV.

Schow, DA: The Impact of Antiandrogen Therapy Prior to Radical Prostatectomy for Localized Carcinoma of the Prostate. SA Cancer Rsch Group Mtg, 7 Jul 95, SA.

Schow, DA: The Impact of Antiandrogen Therapy Prior to Radical Prostatectomy for Localized Carcinoma of the Prostate. Joint Mil Urol Conf, SA TX 14 Jun 95.

Bishoff, JT: Pelvic Lymphadenectomy can be omitted in selected patients with carcinoma of the prostate. Amer Col of Surgeons, Dallas TX Feb 95.

NUTRITIONAL CARE DIVISION

Thomas, VL: Effects of Chromium Supplementation on Plasma Lipid Profiles in Humans. Experimental Biology '95, Atlanta, GA 9-13 Apr 95.

Henley, H: Feeding Enemy Prisoners of War in Operation Desert Storm. AMSC Short Crs SA TX 26-30 Jun 95, Nutrition Care in Operations other than War.

King, N: Defining Roles in Novel Positions Going Public: Presenting and Publishing. AMSC Short Crs, SA TX 26-30 Jun 95, Nutrition Care in Operations other than War.

Sprague, D: Starr County, Texas Project. AMSC Short Crs SA TX 26-30 Jun 95, Nutrition Care in Operations other than War.

Thomas, V: Nutrition Practice Guidelines. AMSC Short Crs, SA TX 26-30 Jun 95, Nutrition Care in Operations other than War.

Skluzacek, L: Somalia. AMSC Short Crs, SA TX 26-30 Jun 95, Nutrition Care in Operations other than War.

Bruns, RD: Nutrition Care Functions within HSSA. AMSC Executive Management Crs, San Antonio 18-22 Sep 95.

Tefft, RJ: (1) Diagnostic Charting. (2) Overview of the Dietetic Internship Programs. AMSC Executive Management Crs, San Antonio, 18-22 Sep 95.

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Sheridan, BJ; Pfaff, J; Johnson, E: Left leg swelling and discoloration. SAEM Nov-Dec 94 issue

Holt, S: Finger Infection. Clinical Pearls, AEM, Nov 95.

Collier, BW; Holt, SJ; Wellford, LA: Narrow complex Tachycardias. Clinics N.A. Emergency Medicine

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#### ABSTRACTS

##### DEPARTMENT OF EMERGENCY MEDICINE

Hemphill, R; et al: Emergency Department follow-up in febrile children: A comparison of two systems.

## DEPARTMENT OF MEDICINE

Durnford, RK; Morris, MJ; Morgan, JA; Kelly, JW; Mego, TS: An experimental rat model of post-pneumonic empyema.

Berneburg, KJ; Peacock, MD: Pleural effusion cell count variability in diagnostic thoracentesis as performed using high negative pressure versus low negative pressure drainage.

Koenig, CD; Battafarano, DF; Older, SA; GRady, EP; Carpenter, MT: Rheumatologic findings in persian gulf war veterans.

Okada, S; Heberle, M; Batzer, W;; Holtzmuller, K: Prevalence of hepatitis C at an inpatient alcoholism recovery facility.

Rudolphi, RS; Mego, DM; Rubal, BJ: Plasma volume, heart rate variability and tilt tablet tests in young patients with vasovagal synope.

Stewart, DA; McCarty, MJ; Vukelja, SJ; Jenkins, TR; Martin, SC: The antiemetic effectiveness of intravenous granisetron in patients receiving preparative high dose chemotherapy prior to autologous bone marrow transplantation.

Borecky, DJ; Stephenson, J; Keeling, JH; Vukelja, SJ: Idarubicin induced pigmentary changes of the nails.

Castro, JT; Champ, JD: Antiphospholipid syndrome.

Dixon, WC; Battafarano, DF; Peacock, MD: Pulmonary alveolar hemorrhage (PAH): A life threatening complication of SLE.

Koenig, CD; McCarty, MJ; Vukelja, SJ: Chronic lymphocytic leukemia in monozygotic twins.

Kwan, MD; Mego, DM; Rubal, B J; LaManna, V: Changes in diastolic function during postural stress in patients with congestive heart failure.

Lewis, A Jr; Wortham, WG: Hemoptysis in a patient with malignant hypertension and congestive heart failure.

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Gilman, J: Sustained monomorphic ventricular tachycardia in active duty aged males without cardiac dysfunction or coronary disease. Amer Col of Physicians Mtg, Oct 94.

Hays, MD; Hoyer, MH; Glasow, PF: Coil embolization of patent ductus arteriosus in newborn piglets. Amer Col of Physicians Mtg, Oct 94.

Latham, RD; Mason, KT: Staged cardiovascular risk assessment in middle aged man at high risk occupations. Amer Col of Physicians Mtg, Oct 94.

Malinowski, TR; Pederson, D; Gilman, JK: Coil embolization of ablation of an accessory pathway guided by the pathway potential following surgery for WPW. Amer Col of Physicians Mtg, Oct 94

Mego, DM; LaManna, V; Moody, JM: Color doppler M-Mode assessment of left ventricular filling in normal individuals.

Miller, L; Ebersole, DG: The Brooke Army Medical Center experience with the Palmaz-Schatz coronary stent. Amer Col of Physicians Mtg, Oct 94.

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Stoll, BC; Ashcom, TL; Johns, JP; Johnson, J; Rubal, BJ: The effects of beta-adrenergic blockade on rest and exercise hemodynamics in patients with mitral stenosis. Amer Col of Physicians Mtg, Oct 94.

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Wright, WT; Moody, JM; Ashcom, TL; Johns, JP; Rubal, BJ: Significance of heart rate and diastolic filling period in patients with moderate mitral stenosis. Amer Col of Physicians Mtg, Oct 94.

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Do, TM; Campos-Esteve, MA; Berry, MA; Rudolphi, RS; Gilman, JK: Pericarditis: Another Cause of Exercise Test Induced ST-elevations.

Ebersole, DG; Miller, LA; Bailey, SR; Kiesz, RS; Wright, WT; Schatz, RA: Long Term Follow Up After Palmaz-Schatz Coronary Stent Implantation.

Ebersole, DG; Miller, LA; Wright, WT: Percutaneous Transluminal Coronary Angioplasty in Elderly Women is Associated with Higher Rates of Complications than in Elderly Men.

Ebersole, DG; Miller, LA; Bailey, SR: Coronary Artery Stenting in Active Duty Soldiers.

Gilman, JK; Setter, SF: Comparison of Older and Younger Patients Undergoing Radio Frequency Ablation for Supraventricular Tachycardia.

Malinowski, TR; Wellford, AL; Khan, NA; Elmore, PR; Rubal, BJ: Serum Creatine Kinase Response After Endomyocardial biopsy in Cardiac Transplant Patients.

Miller, LA; Wright, WT; Nottestad, SY: The Effect of Supportive Interventions on Patient Perception of Back and Arm Pain During Cardiac Catheterization.

Wendt, JR; Rubal, BJ; Bulgrin, JR; Gilman, JK: Electrophysio-logic Effects of Digoxin and Magnesium in Combination.

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Nottestad, SY; Trinkle, JK; Calhoon, J; Sako, EY; Zabalgoitia, M: Serial Transesophageal Evaluation of Right Ventricular Hypertrophy, Pulmonary Vein and Pulmonary Artery Anastomoses in Single Lung Transplant Patients.

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#### Endocrinology Service:

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#### Hematology/Oncology Service:

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Vukelja, SJ; Baker, WJ; Burrell, LM; Lee, N; Jenkins, TR; Rinaldi, D; Myland, RC; Coff, P; McCarty, MJ; O'Rourke, TJ: High-Dose Taxol (T), Cyclophosphamide (CY), and Cisplatin (CDDP) with Stem Cell Support in the Treatment of Metastatic Breast Cancer. 5th Ann Symposium on Cancer in San Antonio, 28 Jul 95, #50, p33.

#### Endocrinology Service:

Carlin, K; Anderson, S; Kennedy, R; Chapa, I: Triac & Tetrac Appear to Stimulate the Growth of HIV in Vitro. NIH CDC ASM Feb 95

Carlin, K; Anderson, S; Kennedy, kR; Chapa, I; Thomason, A; Carlin S. Presented at the 2nd National Conference of Human Retroviruses and Related Infections. Jan 95

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Georgitis, WJ; Alex, NH; Lieberman, M; Johnson, M: Chronic Lymphocytic Leukemia with Thyroid Involvement.

#### Hematology-Oncology Service:

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A Phase I/Pharmacokinetic study of 5-Ethynyluracil Plus 5-Fluorouracil in Cancer Patients with Solid Tumors. AACR #1439. Mar 95, Montreal, Canada.

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Burris, HA; Rothenberg, ML; Anderson, JS; Moore, M; Green, MR; Portenoy RK; Casper, ES; Tarassoff, PG; Storniolo, AM; Von Hoff, DD: Gemcitabine: Effective Palliative Therapy for Pancreas Cancer Patients Failing 5-FU. Gastrointestinal Tract Cancer #470.

Burris, H; Moore, M; Anderson, J; Tarassoff, P; Green, M; Casper, E; Portenoy, R; Modiano, M; Cripps, C; Nelson, R; Storniolo, A; Von Hoff, D: A Randomized Trial of Gemcitabine (GEM) Versus 5FU as First-Line Therapy in Advanced Pancreatic Cancer. Gastrointestinal Tract Cancer, #473.

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Burris, HA; Eckhardt, JR; Weiss, GR; Rodriguez, GI; Fields, SM; Rinaldi, DA; Drengler, RL; Dugan, MH; Batra, VJ; VonHoff, DD: Phase I and Pharmacokinetic Trial of SCH52365 (Temozolomide) Given Orally Daily X5 Days. Phase I Trials, #1579.

Burris, HA; Eckhardt, JR; Rodriguez, GI; Wissel, PS; Fields, SM; Rothenberg, ML; Smith L; Thurman, A; Kunka, RL; Depee, SP; Littlefield, D; White, LJ; VonHoff, DD: A Phase I and Pharmacokinetic Study of the Topoisomerase I Inhibitor GG211. Phase I Trials, #1544.

Cobb, P; Burris, H; Peacock, N; Eckhardt, J; Fields, S; Smith, L; Rodriguez, G; Campbell, L; Finizio, M; Von Hoff, D: Phase I Trial of Losoxantrone Plus Paclitaxel Given Every 21 Days, Phase I Trials, #1545.

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Burris, HA; Khor, SP; Lucas, S; Schilsky, R; Von Hoff, DD; Zhang, R; Spector, T: A Phase I/Pharmacokinetic Study of 5-Ethynyluracil Plus 5-Fluorouracil in Cancer Patients with Solid Tumors. Clinical Investigations, Proceedings of the American Association for Cancer Research, Volume 36, Mar 95, #1439, p241.

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#### Infectious Disease Service:

Garcia, A; Dooley, D: Catheter Bacteremia for Non-Staphylococcal Isolates. IDSA Oct 95.

Joyce, P; McAllister, C: Anemia in HIV patients. IDSA Oct 95.

Plemmons, R; McAllister, C: M. fortuitum infection treated with Clarithromycin. Infec Dis Soc of America

Plemmons, R; McAllister C: M. hemophileum Osteomyelitis in Heart Transplant. Infec Dis Soc of America

Plemmons, R; McAllister, C: (1) Mycobacterium Fortium: Unique Case. (2)

Mycobactium Hemophilum Osteomyelitis. IDSA San Francisco CA 15 Sep 95.

Nephrology Service:

Bakris, CI; Smith, AC; Abbott, KC: Comparison of two Different Dihydropyridine Calcium Antagonists on Albuminuria in Hypertensive Diabetic Subjects: A Randomized Prospective Cross-Over Study.

Pulmonary Disease Service:

Peacock, MD; Houghland, MA; Anders, GT: Incidence of sleep disordered breathing in patients evaluated for gulf war illness. Am J Respir Crit Care Med 1995; 151:A749.

Morris, MJ; Bradley, J; Lee, KY; Roodman, GD; Jenkinson, SG; Bryan, CL: Changes in serum TGF-B1 in nude mice with chronic TNF-a induced pulmonary fibrosis. Am J Respir Crit Care Med 95; 151:A829.

Morris, MJ; Peacock, MD; Mego, D: Pulmonary Hypertension as a Risk Factor for Hemorrhage from Transbronchial Biopsy. Chest 1995;108:182S.

Rheumatology Service:

Grady, EP; Carpenter, MT; Battafarano, DF; Older, SA: Rheumatic Findings in Persian Gulf Veterans.

**DEPARTMENT OF NURSING**

Connelly, L: A Naturalistic Study of a Nursing Orientation Program

**Posters presented at the Regional Research Day sponsored by BAMC 12 May 95:**

Connelly, L: A Qualitative Study of factors Conducive to Retention of Nurses Likely to Leave an Acute Care Facility

Reilly, M: Visual Imagery as an adjunct to Narcotic Analgesia in the Perioperative Period.

Connelly, L: A Naturalistic Study of a Nursing Orientation Program Midwest Nursing Research Society Annual Conference.

**DEPARTMENT OF OBSTETRICS-GYNECOLOGY**

Higby, K; Suiter, CR: A Comparison Between two screening methods in the detection of microproteinuria. 15th Annual Society of Perinatal Obstetricians Mtg, Atlanta, GA 23-28 Jan 95

Benrus, M; Higby, K; McCoy, C: Pathophysiology of terbutaline induced glucose tolerance. 15th Annual Society of Perinatal Obstetricians Mtg, 23-28 Jan, Atlanta, GA



Gehlbach, D: Preventive Care in the Postmenopausal Woman  
Polycystic Ovaries and Hirsutism  
Hyperprolactinemia: When to Treat  
At Controversies in Women's Health care, Puerto Vallarta, Mexico 23 Feb 95.

#### DEPARTMENT OF PATHOLOGY

Lerud, KS; Frost, AR; Tabbara, SO; DelVecchio, D: Cytomorphology of Cystic Parathyroid Lesions. Acta Cytologica, Nov 94.

#### PHYSICAL MEDICINE AND REHABILITATION SERVICE

Hobbs, C; Harvey, K; Barillo, D; Mozingo, D; Pruitt, B: Physical & Occupational Therapy Support of a Burn Mass Casualty Incident: Implications for Planning.

Barillo, D; Harvey, K; Buescher, T; Mozingo, D; Cioffi, W; McManus, W; Pruitt, B: A Treatment Protocol for the Management of Multiple Hand Burns During Mass Casualty Incidents.

Henderson, NE: Postural Stability in Essential Tremor. 4th International Congress of Movement Disorders Vienna/Austria, 17-21 Jun 95.

#### DEPARTMENT OF SURGERY

##### Cardiothoracic Surgery Service:

Lisagor, PG: First Annual 1995 Trauma Symposium, OTSG, United States Army, San Antonio, TX, 13-15 Sep 95, "Operations Other Than War".

##### Ophthalmology Service:

Rivera, DR; Campagna, JA: Apraclonidine 0.5% vs Apraclonidine 1.0% for the control of Intraocular Pressure Elevation after Argon Laser Trabeculoplasty. 1995 ARVO

##### Otolaryngology Service:

Ramirez, SG; Teller, DC;: Skin Excision in Rhytidectomy.

Liening, DA: The Effects of Linear Acceleration on Distortion Products Otoacoustic Emissions in Human Ears.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number C-18-88 Status: Ongoing

Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

Start date: 16 Dec 88	Estimated completion date:
Principal Investigator: Gerald A. Merrill	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Paul M. Horowitz, PhD, UTHSC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$4,690.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitomes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

Technical Approach: The study plan is to develop a series of antibodies to use in an attempt to better understand the structure-function relationships of a model protein, rhodanese (thiosulfate; cyanide sulfurtransferase). Knowledge

C-18-88 (continued)

of the relationships of between protein structure and protein functions will provide insight into the manipulation of proteins that have medical relevance, including hormones and enzymes. Such knowledge might then permit synthesis via genetic engineering of designer rescue proteins that could be used therapeutically.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-4-91 Status: Ongoing

Title: Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin

Start date: 16 Nov 90	Estimated completion date:
Principal Investigator: Gerald A. Merrill, Ph.D	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To develop a solid phase enzyme-linked sandwich assay of high sensitivity for the detection and quantitation of ricin which is based on avidin-biotin technology, enzymatic generation of ATP, and the sensitivity of photon counting detection of ATP via the bioluminescent luciferin-luciferase (firefly).

Technical Approach: A solid phase enzyme linked immunoassay for quantitation of ricin utilizes the chemiluminescence of a luminol derivative which emits light at alkaline pH following the removal of a phosphate group by the action and concentrate the toxin which may be present in very low concentrations. The quantitation of ricin that is immobilized involves addition of biotinylated anti-ricin followed by excess avidin-alkaline phosphatase which binds to biotin very tightly. The quantitation of the alkaline phosphatase can be either colorimetric or can be measured via luminescent methods with increased sensitivity using AMPPD as the substrate.

Progress: Modification of the assay to detect ricin with increased sensitivity has been proposed. The modification involves an immuno-PCR technique which has been designed. The use on ricin detection will be as a model for use in detection of botulism toxin which requires extreme sensitivity, but which cannot be developed at BAMC due to the restrictions on use of botulism toxin. A request for \$10,000 in funding for FY 1996 has been submitted to USAMRIID for development of the assay system.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-25-91 Status: Ongoing

Title: Automated Screening of Western Blot Densitometry Scan for the Detection of Type-Specific Herpes Virus Antibodies.

Start date: 6 Feb 91	Estimated completion date: 6 Feb 95
Principal Investigator: John A. Ward, PhD	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Julia K. Hilliard, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if the application of digital signal processing and artificial neural networks (ANN) can be used to distinguish B virus antibodies from herpes simplex antibodies in human sera.

Technical Approach: Train ANNs with an input consisting of preprocessed censitometer scans of western blots (WBs) from serum samples run against B virus antigen. Preprocessing involves the application of signal analysis techniques: mapping the densitometer scans to a common molecular weight axis, filtering to remove high and low frequency noise and emphasize peaks, normalizing to eliminate amplitude distortion, windowing to zero the high and low molecular weight ends of the scan, and cross-correlating and aligning the signals to eliminate phase shifting.

Progress: Two techniques (correlation analysis and ANNs) have been tested. Both presented problems. Wbs showed higher correlations between different sera run on the same blot than between the same sera run on different blots. ANNs were susceptible to phase shift errors and noise not represented in the training set. In the next year, Wbs of control (BV + rhesus, BV-rhesus, BV + human, HSV1 + human, HSV2 + human and negative human) sera and 180 sample (6 X 30) sera will be run against BV, HSV1 and HSV2 antigens. Since the 35 to 73 kD region appears to be critical for discrimination between virus types, each WB will be divided into three regions (200 to 73 Kd, 73 to 35 Kd, 35 to 14.3 Kd). This will provide 6 X 3 X 3 = 54 regional Ag-Ab cross correlation coefficients which will be input to a neural network. This will provide an internal control for variation in batches of antigen, control sera and immunoelectrophoretic technique.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-49-91 Status: Terminated

Title: The Use of Polymerase Chain Reaction (PCR) to Detect Hepatitis C in Units of Donor Blood

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS Victor Tryon, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Apr of ea yr Review results:

Objective(s): To develop an assay to test for Hepatitis C virus (HCV) in units of donated blood collected at BAMC, using polymerase chain reaction and robotic technology.

Technical Approach: We intend to develop methods which combine the technology of robotics and high sensitivity and specificity of the polymerase chain reaction (PCR) to detect Hepatitis C virus (HCV) in approximately 300 units of donor blood daily. We will develop the system such that test results will be available the same day the units are drawn.

Progress: 4/95: Protocol never fully approved. Equipment not obtained. Request termination of protocol.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-58-91 Status: Terminated

Title: Preparation of Large and Small Unilamellar Vesicles and Interaction with Magainin

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Earl Grant, Jr., MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish the means and verify the methodology that will produce well-defined liposomes for use as model membranes for the study of protein/peptide-lipid interactions and as potential drug carriers to aid in cancer therapy.

Technical Approach: Large unilamellar vesicles of various lipid compositions will be prepared by the reverse phase ether evaporation method. Small unilamellar vesicles of various lipid compositions will be prepared by sonication. The functional integrity of the vesicles can be assessed by monitoring the release of entrapped 6-carboxyfluorescein in the absence and presence of Triton X-100.

Progress: We continue to maintain the capability to produce small unilamellar vesicles, however, we do not have the equipment to prepare large unilamellar vesicles by the reverse phase ether evaporation method. The needed equipment is being requisitioned and alternative methods are being investigated.  
 Mar 95 Annual Review: Termination requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-91-91 Status: Ongoing

Title: Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, MAJ, MS	Facility: Brooke Army Medical Center
Department/Service: Department of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Oct of ea yr Review results:

Objective(s): To develop methods which combine the speed and precision of robotics and the high sensitivity and specificity of gene amplification strategies to detect RNA from the hepatitis C virus in 300 units of volunteer donor blood daily.

Technical Approach: Research in this proposal is designed to adapt gene amplification techniques to a clinical diagnostic format capable of operating at a process level (300 plus tests per day). Research to be conducted includes identification and development of unique nucleic acid probes and primers, testing of amplification techniques, development of solid phase nucleic acid capture assays; adaptation of radiometric assays to machine-read fluorometric testing and side-by-side comparison of the molecular diagnostic assays developed versus the standard serological assay.

Progress: We are currently awaiting approval of research funding by Medical Research and Development Command.

Oct 94 Annual Review: Keep ongoing.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-20 Status: Ongoing

Title: Establishment of a Polymerase Chain Reaction (PCR) Nucleic Acid Amplification capability Within the Department of Clinical Investigation, BAMC

Start date: Feb 93	Estimated completion date: Feb 95
Principal Investigator: Lawton A. Seal, LTC, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): N/A
Key Words: Polymerase chain reaction Taq polymerase, Ethidium bromide Agarose gel electrophoresis	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: Approved \$2725.00 Used \$1457.01

Number of subjects enrolled during reporting period: N/A  
Total number of subjects enrolled to date: N/A  
Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To establish a working PCR gene amplification capability. It will result in the capability to specifically amplify a positive control bacteriophage gene without contamination by irrelevant nucleic aids. Demonstration of the desired product will include separation of the amplification products by agarose gel electrophoresis and identification by product size as seen after ethidium bromide staining.

Technical Approach: No subjects involved. Controls for the reaction are contained within the kits and include a distilled water negative control and a specific bacteriophage gene positive control. Experimental design/methods; data collection and details included in protocol.

Progress: The initial PCR was successfully accomplished and resulted in the contamination-free amplification of a Lambda bacteriophage gene. Continuing to optimize those reactions as well. Anlysis of amplification products by agarose gel electrophoresis and ethidium bromide staining has been successful and both this and PCR are being taught to DCI staff.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-95 Status: Ongoing

Title: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid

Start date: 16 Jul 93	Estimated completion date:
Principal Investigator: Jenice N. Longfield, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): Immunization of one volunteer who will be working with botulism toxin at Fort Detrick, MD.

Technical Approach: The vaccine will be obtained from the centers for Disease Control (CDC). The initial vaccination series will be given 0.5 ml deep subcutaneously at 0, 2, and 12 weeks Forty-eight hours after each injection, the injection site will be observed by the principal investigator. The first booster will be given 0.5 ml deep subcutaneously 12 months after the first injection of the initial series. Subsequent boosters will be given 0.5 ml deep subcutaneously at 2 year intervals, based on antitoxin titers. Any reactions or side effects will be observed and reported to the CDC.

Progress: One subject has received the initial series of 4 immunizations given as 0.5ml deep subcutaneous doses at 0, 2, 12 weeks and booster at one year. After 12th week, neutralization titer was 0.08 units; 0.02 is considered protective. Booster given at one year has not been re-titered.

Jul 95: Booster given after one year (29Nov94) has a neutralization titer of 9.00 units/ml.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-75 Status: Ongoing

Title: Evaluation of Terry Fox Metho-Cult H433 and Gibco BRL Human Bone Marrow Stem Cell Differentiation Media

Start date:	Estimated completion date:
Principal Investigator: Enid Davey	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s): Svetislava J. Vukelja, M.D.
Key Words: bone marrow stem cells, Gibco BRL Medium	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Mar of ea yr Review results:

Objectives: To determine if Gibco BRL Medium supports greater differentiation of bone marrow stem cells than Terry Fox Medium.

Technical Approach: The study will be conducted in two phases as outlined in protocol.

Progress: A preliminary study has been done using Terry Fox's Metho-Cult #4431, as to growth, size and differentiation, compared to Gibco-BRL media.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-94 Status: Ongoing

Dietary Protein Needs and Protein and Amino Acid Metabolism of Military Women and Men

Start date: 21 Jun 95	Estimated completion date:
Principal Investigator: Kathleen J. Motil, M.D.	Facility: Baylor Col of Medicine & BAMC
Department/Service: Clinical Investigation	Associate Investigator(s): Manuel C. Morales, M.D. Curtis L. Yeager, MAJ MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To examine the adaptive responses of body protein and amino acid metabolism in military women to reduced protein intakes as a means to assess dietary protein needs, and to determine the extent to which the military woman's body composition and physical performance influence the magnitude of her protein needs. Specific aims are outlined in proposal.

Technical Approach: Hypothesis is that 1) dietary protein requirements are higher in military than in civilian women because of the differences in body composition and physical performance between these two groups, 2) dietary protein requirements will be similar between military women and men after accounting for differences in their body composition and physical performance in the occupational and field setting, and 3) dietary protein requirement of military women and men are equally higher in the field than in the occupational setting.

Progress: Jun 95: Funding problems.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-126      Status: Ongoing

Investigation of Possible Changes in the Concentration of Soluble Leukocyte Selectin (sL-selectin) in Stored Blood

Start date: 16 Aug 95	Estimated completion date:
Principal Investigator: Melville Bradley, M.D. Trans Intern	Facility: BAMC
Department/Service: Dr. Bradley is a Transitional Intern	Associate Investigator(s): Jerry Merrill, PhD Jenice Longfield, M.D. Daniel Smith
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To see whether sL-selectin concentrations increase over time in stored blood (at tie 0 hr and at 48 hrs), and if so, to speculate about its possible role in contributing to the phenomenon of post-transfusion immunosuppression. The null hypothesis of this study is that there will not be an increase in sL-selectin concentrations in stored blood over time.

Technical Approach: As outlined in the protocol.

Progress: This is a new study. There is no data to report.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-143 Status: Ongoing

Design and evaluation of rapid assays for select antibody and antigen specificities throughout the course of B virus infection

Start date: Sep 95	Estimated completion date:
Principal Investigator: John A. Ward, PhD	Facility: BAMC
Department/Service: Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate rapid assays designed to identify selected antibody and antigen specificities throughout the course of infection.

Technical Approach: Specifics are outlined in protocol.

Progress: This is a new study. There is no data to report.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-93-40      Status: Ongoing

Title: An Evaluation of Nafcillin for the Initial Treatment of Cellulitis

Start date: 24 Dec 92	Estimated completion date:
Principal Investigator: Curtis Hunter, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): Kevin Rodgers, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10

Total number of subjects enrolled to date: 10

Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the effectiveness of oral antibiotics in treating cellulitis and preventing subsequent admission of patients with cellulitis. Compare the efficacy of an initial parenteral dose of antibiotics in preventing the subsequent admission of patients with cellulitis, as compared to those patients who do not receive parenteral antibiotics. Compare the efficacy of an initial dose of parenteral antibiotics in treating more rapidly those patients with cellulitis, as compared to those patients who do not receive antibiotics.

Technical Approach: This will be a randomized, prospective study. Patients with cellulitis deemed appropriate for outpatient therapy will be randomized at the beginning of the study to one of two treatment regimens. Patient eligibility, exclusion criteria and study plan outlined in protocol.

Progress: The investigator has PCS'd. The exact status is unknown.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-06 Status: Ongoing

The Efficacy of Nebulized Dexamethasone in the Treatment of Acute Asthma

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Marco Coppola, D.O.	Facility: DAH
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of nebulized albuterol with and without nebulized dexamethasone for the emergency department treatment of acute asthma in an adult population.

Technical Approach: Inhaled steroids have been used extensively for the adjunctive outpatient treatment of chronic asthma. However its efficacy in the treatment of acute asthma has not been well established. This investigation will examine if the addition of dexamethasone to nebulized albuterol treatments will provide quicker relief from the acute asthma episode. Other pertinent background information is outlined in protocol.

Progress: Nov 95: Dr. DiCiro the original PI has left DAH and therefore Dr. Coppola has become the PI. Of the 19 patients enrolled, going to use them as a pilot study. Have encountered some problems and looking to improve the study. Is currently on hold status. If changes needed will bring back before the Committees.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-34 Status: Ongoing

## Comparison of Outpatient Treatments for Pyelonephritis

Start date: 1 Feb 95	Estimated completion date:
Principal Investigator: Michael P. Applewhite, D.O.	Facility: BAMC/WHMC/DACH
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To supply further evidence that outpatient management of acute pyelonephritis is a safe and effective way to treat a wide range of otherwise healthy men and women. Although many Emergency Departments are already treating patients with pyelonephritis on an outpatient basis, there remains controversy about the safety, efficacy, and the population of patients for whom this is safe. This project would attempt to show the population in whom it is safe to treat as an outpatient, as well as safe choices and duration of antimicrobial therapy.

Technical Approach: The hypothesis in this study is to prove that outpatient management of healthy individuals with pyelonephritis is both safe and effective using a two week course of either oral plus IV antibiotics or using oral antibiotics alone. Men and women presenting to the Emergency Department with signs and symptoms suggestive of pyelonephritis will be considered for the study.

Progress: There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-36 Status: Ongoing

## Follow-up Compliance for Febrile Children

Start date: 1 Feb 95	Estimated completion date:
Principal Investigator: Robin R. Hemphill, USAF MC	Facility: BAMC
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the rates of compliance to follow-up in a population of febrile children. (NULL HYPOTHESIS: Parents of febrile children will not follow-up as directed by the physician when they have to make their own appointments.)

Technical Approach: Hypothesis of this study is that the parents of ill children in the military have access to free medical care, but it may not be this free care that causes the military to have better rates of follow-up compliance than civilian institutions.

Progress: There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-127 Status: Ongoing

Use of H1/H2 Blockers in Treatment of Acute Urticaria

Start date: 16 Aug 95	Estimated completion date:
Principal Investigator: Michael Brooks, M.D.	Facility: BAMC
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the efficacies of oral cimetidine and diphenhydramine alone and in combination for the treatment of acute urticaria.

Technical Approach: A prospective, randomized, double-blind study will be instituted. Will utilize any patient at least 18 years of age or any active duty personnel with acute urticaria of any etiology and of any duration. All subjects will be treated in compliance with all applicable FDA and HHS guidelines. Exclusion criteria, and detailed specifics are outlined in protocol.

Progress: There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-60-86 Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start date: 25 Jun 86	Estimated completion date:
Principal Investigator: David Dooley, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s):
Key Words: HTLV-III	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 570  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.).

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for Future testing.

Progress: The study continues; approximately 570 patients have been enrolled. Again, his is a descriptive study of Army HIV patients and the clinical cause of their HIV infection.

Jun95: Continuing to add patients Army-wide.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-52-87 Status: Ongoing

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex Vivo Marrow Treatment with 4-hydroxyperoxycyclophosphamide (4-HC).

Start date: 13 May 87	Estimated completion date:
Principal Investigator: Svetislava J, Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 4  
Periodic review date: May of ea yr Review results: Continue

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Study ongoing for eligible patient enrollment.

May95: Patient expired day 78 post high dose chemotherapy. She died from sepsis.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-62-87 Status: Ongoing

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol).

Start date: 25 Jun 87	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr, LTC, MS Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$19,404.00

Number of subjects enrolled during reporting period: 39

Total number of subjects enrolled to date: 206

Periodic review date: Jun of ea yr Review results: 36 patients done

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion. (This is the master protocol for the autologous bone marrow transplant program.

Progress: Study remains ongoing for eligible patient enrollment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-64-87 Status: Completed

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance.

Start date: 21 Jul 87	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 48  
Periodic review date: 19 Oct 92 Review results: Completed

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a  $D_LCO$ , cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GM stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMNs, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: No new patients added. Dr. Johnson requests that protocol be closed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-19-88 Status: Ongoing

Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: Albert M. Thomason, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: 19 Mar 91 Review results: Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type I diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: We are still lacking in recruitment of volunteers. More effort will be made to recruit volunteers which as stated previously is very difficult without being able to provide some kind of compensation.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-63-89 Status: Completed

Title: What is the Value of Fecal Hemoccult Blood Tests Performed at the Time of Digital Rectal Examination

Start date: 26 Apr 89	Estimated completion date:
Principal Investigator: Shailesh Kadakia, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Charles Cohan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$750.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 101  
Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): To determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal appearing stool obtained at rectal examination are eligible. Patients are offered the standard care which includes full evaluation of the lower GI tract and possibly of the upper GI tract. Stool Hemoccult II samples are collected on 3 consecutive days in the usual manner with standard dietary and drug restrictions. Hemoquant assays to determine the total amount of hemoglobin in the stool is also determined on the same stool samples. Findings at colonoscopy and/or upper endoscopy are noted.

Progress: 4/95 As of this date a total of 101 patients have been enrolled in study. This includes those at both BAMC and Tripler AMC. Of 101 patients, 82 were both hemoccult and Hemoquant negative, and 19 were either hemoccult or Hemoquant or both positive. Of the 82 patients with hemoccult and Hemoquant both negative, a total of 34 patients had endoscopic lesions found and in the group of 19 patients with either hemoccult or Hemoquant or both being positive, 15 had lesions on endoscopy found to be significant. This difference was statistically significant at a value of  $p=0.003$ . This study is now closed at present and we expect to analyze more data in reference to the symptoms, as well as intake of NSAIDs. Final manuscript in preparation.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-107-89 Status: Completed

Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in Malignant Pleural Effusions.

Start date: 14 Aug 89	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16

Total number of subjects enrolled to date: 20

Periodic review date: Aug of ea yr Review results: Completed

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A in patients with malignant pleural effusions.

2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: Toxicity consists of mild flu-like symptoms being observed at the current dose level of 50 million units/m<sup>2</sup>. Anticipate closure at this dose level after enrollment of another 2-4 patients.

Aug 95: This trial is completed with a minimally tolerated dose of 50 million units/m<sup>2</sup>. Dose-limit toxicities included flu-like symptoms and fevers, but were mild. Cost was a significant factor in supply at this level. Efficacy was observed at the higher levels and additional studies are being planned.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-3-90 Status: Ongoing

Title: Differences in Response to Thiazide-Induced Hyponatremia by Gender.

Start date: 7 Dec 89	Estimated completion date: Jun 94
Principal Investigator: MAJ Kevin C. Abbott, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s): Steven F. Gouge, MAJ, MC Daniel Gavin, CPT, MC
Key Words: Hyponatremia, gender, thiazides, free water clearance, antidiuretic hormone	
Cumulative MEDCASE cost: \$4800	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7

Total number of subjects enrolled to date: 9

Periodic review date: Dec of ea yr Review results:

Objective(s): To determine the differences, if any, between healthy elderly males and females in response to a water challenge test before and after the administration of hydrochlorothiazide.

Technical Approach: Eight men and eight women (power analysis projections from current results allowed this change from the original estimate of ten men and ten women), age 55 and above, with no concurrent hypertension or diabetes will be studied. Baseline blood tests will be drawn for serum sodium and potassium levels as well as thyroid function test6s and a baseline water challenge test in which they will drink 20 cc/kg of ideal body weight of fresh water followed by a four hour timed urine collection for urine electrolytes and osmolality. Before the water load and after four hours, blood samples will be drawn for serum sodium, potassium, antidiuretic hormone, prolactin, diuretic levels and atrial natriuretic factor.

Progress: Principal Investigator has been deployed. Protocol status unknown.  
Dec 94: Annual Review requested Ongoing but no detailed info furnished.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-24-90 Status: Ongoing

Title: Induction of TNFa and IL-1 in Human Tuberculosis.

Start date: 5 Feb 90	Estimated completion date:
Principal Investigator: Gregg T. Anders, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary Disease	Associate Investigator(s): J. William Kelly, MAJ, MC C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$18,300.00 (R&D)

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: Continue

Objective(s): The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin-1 (IL-1) production association with human tuberculosis. Peripheral blood monocytes cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

Technical Approach: Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

Progress: Study remains ongoing for patient accrual.  
 Feb 94: Annual Review - Ongoing requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-40-90 Status: Ongoing

Title: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: William G. Wortham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Mar of ea yr Review results: Continue

Objective(s): To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if the decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

Technical Approach: Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hour urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hour creatinine. In addition, they will undergo a nuclear determination via plasma clearance, I<sup>131</sup> Hippuran and DTPA to determine renal blood flow as well as GFR via radionuclide study 4-6 hours prior to catheterization, they will receive half-normal saline at approximately 125 cc/hour if not contraindicated by volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hour urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An I<sup>131</sup> Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hours post cardiac catheterization.

Progress: Study ongoing but still has not been actively pursued due to time

C-40-90 (continued)

constraints of myself, Nuclear Medicine Service and significantly by inability to recruit patients from the Cardiology Service. Two patients were recently recruited. Protocol is progressing slowly.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-71-90 Status: Ongoing

Title: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 11  
 Periodic review date: Jun of ea yr Review results: Continue

Objective(s): To determine the toxicity, time to marrow reconstitution, responsive rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Jun 95: Oct 93-Oct 94 - One patient done with testicular Ca. Would like to keep this study open for a rare patient.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-90-90 Status: Ongoing

Title: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (ACL) and Acute Lymphocytic Leukemia (ALL).

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 6  
 Periodic review date: Aug ea yr Review results:

Objective(s): To determine the effects of autologous transplantations with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

Technical Approach: Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

Progress: 4-HC is no longer available for purging. So we continue to do the transplant without 4-HC purge (addendum was submitted more than 1 1/2 years ago; however many patients have BM stored that was previously purged when 4-HC was available. Thus, we need to keep this protocol open. All patients have relapsed to date.

Aug 95: No change.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-11-91 Status: Ongoing

Title: The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema.

Start date: 3 Feb 93	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Pulmonary	Associate Investigator(s): Kevin Kimke, CPT, MC Wayne Honeycut, MAJ, MC H.M. Blanton, MAJ, MC Gregg T. Anders, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
 Total number of subjects enrolled to date: 58  
 Periodic review date: Feb of ea yr Review results:

Objective(s): To study the effects on lung mechanics of breathing 50% oxygen balance nitrogen versus breathing 21% oxygen balance nitrogen in a group of emphysematous patients with moderately severe disease.

Technical Approach: Patients undergo forced vital capacity, thoracic gas volume, airway resistance and compliance measurement before and after breathing 21% O<sub>2</sub> and 50% O<sub>2</sub> (double-blinded).

Progress: No new patients have been added. Recently Southern Medical Journal accepted a manuscript containing some of this work. Protocol remains open.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-13-91 Status: Ongoing

Title: A Randomized, Double-Blind, Placebo Controlled Trial of the Effect of Lovastatin on the Incident of Primary Coronary Heart Disease in Patients with Mild to Moderate Elevations in Total and LDL-Cholesterol in Combination with Low HDL-Cholesterol.

Start date: 11 Dec 90 Estimated completion date: 1998

Principal Investigator: Joe M. Moody, COL, MC Facility: Brooke Army Medical Center, Texas

Department/Service: Department Medicine/Cardiology Associate Investigator(s): Edwin J. Whitney, M.D., WHMC

Key Words:

Cumulative MEDCASE cost: Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2 Aug 94  
Total number of subjects enrolled to date: Over 5 thousand = 6,609  
Periodic review date: Jan of ea yr Review results: safety board review -> continue study no adverse safety data yet

Objective(s): To investigate whether chronic treatment with lovastatin in patients without clinical evidence of coronary heart disease, slight to moderately elevated total and LDL cholesterol and low HDL-cholesterol will decrease the rate of fatal CHD of nonfatal myocardial infarction over a period of at least five years.

Technical Approach: Participants will be asked to maintain a standard low-fat and low-cholesterol diet throughout the study under the guidance of a dietician. Participants will be randomly assigned to either the placebo group or treatment group. The later group will receive 20 or 40 mg of lovastatin. Following initial evaluation at the Wilford Hall Wellness Clinic, they will be asked to return at six week intervals for the first eighteen months and then every six months thereafter. Lab tests will be performed at every follow-up visit.

Progress: There have been no complications, misadventures or adverse drug reactions as defined by regulation. Specifically, there have been 110 patient withdrawals due to CPK or liver function elevations. Twenty-nine patients have been withdrawn (2%). Studies of similar nature have encountered withdrawal of eight to twelve percent with an average of ten percent. This withdrawal ratio is exceptionally low. None of the patients were withdrawn due to events attributable to the study medication. Due to lagging

C-13-91 continued

recruitment, approval to enroll civilians and civil servants was obtained from the Air Force Surgeon General, as well as the Air Staff on 26 June 1991. Civilian participants do not become eligible for care in the military system by participating in this study. Enrollment is now 18.2% complete with 1,225 men (84%) and 232 women (16%). Estimated completion date is May 1997. As of 2 August 94: Since December 1993, enrollment stable at 6600 patients. There are over 90 endpoints, no analysis yet, safety data not adverse.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-14-91 Status: Ongoing

Title: Active Immunization of Early HIV Patients with Recombinant GP-160 HIV Protein: Phase II Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy.

Start date: 8 Jan 91	Estimated completion date:
Principal Investigator: Charles E. Davis, Jr., MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 47  
 Total number of subjects enrolled to date: 59  
 Periodic review date: Jan of ea yr Review results:

Objective(s): To conduct a Phase 2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, GP160 candidate vaccine, in patients with early HIV infection (Walter Reed Stage 1-2). Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immuneresponsiveness; and 3) to determine the clinical efficacy of immunization with GP160 in the treatment of early HIV infection.

Technical Approach: As outlined in the study protocol.

Progress: All patients are four years into followup. Recommend continuation for continued followup.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-28-91 Status: Ongoing

Title: Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Wayne T. Honeycutt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13  
 Total number of subjects enrolled to date: 33  
 Periodic review date: Feb of ea yr Review results:

Objective(s): To determine whether exercise induced oxyhemoglobin desaturation in moderate to severe chronic obstructive pulmonary disease (COPD) patients can predict those who will have significant nocturnal desaturation.

Technical Approach: Approximately 40-50 subjects will be studied. Each patient will undergo an initial history and physical examination. Pulmonary function tests will be performed on the SensorMedics Horizon System to include pre- and post-bronchodilator forced vital capacity (FVC) and FEV1. Lung volumes and diffusion capacity for carbon monoxide will be measured. Resting arterial blood will be obtained in the supine position on room air. Desaturation with exercise will be evaluate during cardio-pulmonary testing using the Minolta Pulse-Oximeter. Nocturnal respiratory excursions, nasal airflow, ECG and oxyhemoglobin saturation will be monitored with an ambulatory system.

Progress: Request protocol to continue as ongoing.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-11 Status: Ongoing

Title: Household Transmission of Hepatitis C Virus in Military Populations

Start date: Jan 92	Estimated completion date: Dec 95
Principal Investigator: COL Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Thomas Kepczyk, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12 - consisting of  
Total number of subjects enrolled to date: patients and 9 household  
Periodic review date: Jan of ea yr Review results: contacts

Objective(s): Study will consist of enrolling anti-HCV-positive individuals and anti-HCV-negative individuals with a diagnosis of chronic NANB hepatitis and their household contacts.

Technical Approach: Three (3) index cases tested positive for anti-HCV. The serum samples were submitted for further testing to include anti-HCV by ELISA, as well as by RIBA and finally by PCR to detect HCV-RNA. These samples were obtained from 3 index cases and 9 additional household contacts. Total of 56 index patients from BAMC, FAMC, WRAMC, and TAMC have been included in the study with 84 household contacts.

Progress: Since the last reporting on 15 Dec 93, no further patients have been enrolled in th study at BAMC. The data has been analyzed in 50 anti HCV positive patients and 83 household members from four Army Medical Centers to include BAMC, TAMC, Fitzsimons and Walter Reed and US Army Medical Research Institute of Infectious Diseases at Ft Dietrick. Of the total index cases as well as household contacts, 6 spouses have anti HCV, two of the six had independent risk factors for HCV infection and were excluded from statistical analyses. Thus, four of 47 spouses had detectable HCV markers of infection, a rate of 8.5 percent. This prevalence was greater tan the 0.54 percent observed among health blood donors for a P value of less than 0.0001. HCV RNA

C-92-11 (continued)

was present in 43 of 50 (86%) index patients and in 4 of 6 (67%) infected spouses. Preliminary six month follow-up data in 18 families with 0 conversion in male spouse (none sexual partner) complete family member. These results show that household exposure to a HCV-infected family member is a risk factor for recording HCV infection, particularly among sexual partners of HCV infected individuals.

This paper has been submitted for publication to Viral Hepatitis and liver disease journal and has been accepted for publication.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-14 Status: Ongoing

Title: Cell Culture Model to Test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Isidoro Chapa
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if reversible hypothyroidism can be induced briefly in euthyroid patients, conceivably normal cells can be induced into a hypometabolic state while the diseased cells continue at their baseline or near baseline metabolic level.

Technical Approach: Cell cultures will be grown from prostate tissue recently removed with TURP by urology and documented prostate cancer present by pathological exam.

Progress: The data has been written up and submitted for publication which is pending at this time. (Presented in abstract already)



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-18 Status: Ongoing

Title: The Natural History of HIV Infection and Disease in United States Military Beneficiaries

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 131  
 Total number of subjects enrolled to date: 184  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): a) To systematically document the natural disease progression in individuals with HIV infections in a general military population. b) To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

Technical Approach: Proposal is to organize information in a data base now being routinely collected on HIV patients into a data base, henceforth referred to as the BAMC Natural History Study, in such a way that more scientifically valid information will be forthcoming and safeguards to patient confidentiality are met.

Progress: 184 BAMC patients have been enrolled to date. This protocol is a component of an overall Tri-service natural history study which now has a registry of over 1800 patients.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-27 Status: Ongoing

Title: Analysis of Foot Surface Stress in Parachute Landing Falls

Start date:	Estimated completion date: Jan 95
Principal Investigator: MAJ James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopedics	Associate Investigator(s): Dr. John A. Ward, PhD COL Allan L. Bucknell, MC
Key Words:	
Cumulative MEDCASE cost: \$1000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

Technical Approach: 80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H<sub>2</sub>-blockers.

Progress: Twenty-two patients are enrolled with 18 of 22 reaching the 2 year endpoint of the study. To date, no change has been noted in Barrett's epithelium from baseline measurement at reference tattoo at 3, 9, 15, or 24 months. No complications reported due to the study. Project continuation of the study an additional 1 1/2 years to bring all study patients to the 2 year endpoint.  
Jul 95: Study reopened.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-30 Status: Ongoing

Title: Regression of Metaplastic Esophageal Epithelium With Omeprazole

Start date: Feb 92	Estimated completion date: Jan 95
Principal Investigator: MAJ Richard Shaffer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh Kadakia, MC MAJ John G. Carrougner, MC
Key Words:	
Cumulative MEDCASE cost: \$1000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 21  
Total number of subjects enrolled to date: 6  
Periodic review date: Feb of ea yr Review results:

Objective(s): To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

Technical Approach: 80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H<sub>2</sub>-blockers.

Progress: Twenty-two patients are enrolled with 18 of 22 reaching the 2 year endpoint of the study. To date, no change has been noted in Barrett's epithelium from baseline measurement at reference tattoo at 3, 9, 15, or 24 months. No complications reported due to the study. Project continuation of the study an additional 1 1/2 years to bring all study patients to the 2 year endpoint.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-92-41

Status: Ongoing

Title: Quantification of T3 Receptors in Human Cancer Tissue Compared to the Tissue from the Clear Margin of the Same Surgical Specimen

Start date:	Estimated completion date:
Principal Investigator: Kevin Carlin, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: _____	
Periodic review date: <u>Mar of ea yr</u> Review results: _____	

Objective(s): Patients whose medical care has already dictated a surgical procedure for diagnosis and/or therapy of a possible cancer will be considered as a possible candidate to enter the study. There will be no exclusion factors. The only impact to patients for participation is the tissue that was to be removed any will undergo additional analysis.

Technical Approach: Patients with known or strongly suspected cancers who are undergoing surgery for diagnosis and/or therapy will have postop examination and testing of a representative sample of their mass and the clear margin. Samples will have their T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors in the clear margin than in the cancer cells.

Progress: No update furnished.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-53 Status: Ongoing

Title: Core Protocol for HIV Developmental Diagnostic (Adult).

Start date:	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Donald S. Burke, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 90  
 Total number of subjects enrolled to date: 90  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): a) To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status. b) To develop and evaluate new and/or improved laboratory methods for assessing the virus-specific immune response to HIV infection, and to correlate detection of virus-specific antibody or cell mediated immune responses with clinical status.

Technical Approach: Under this protocol, the patient will be asked to give informed consent that his/her blood can be used for the general purpose of development and evaluation of virologic and immunologic techniques, and that his/her clinical records can be reviewed in order to correlate test results with his/her clinical condition. Solicitation of patients will be done in the Infectious Disease Clinic by a protocol manager on the Infectious Disease Clinic.

Progress: Approximately 146 subjects have been enrolled to date. Serum and cells from these patients have been banked for use in development of diagnostic methods.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-68 Status: Ongoing

Title: Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy.

Start date: Jul 92	Estimated completion date: Jun 97
Principal Investigator: Gail L. Seiken, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words: Nephrotic Syndrome Membranous nephropathy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jul of ea yr Review results: N/A

Objective(s): 1) To prospectively examine the incidence of thrombotic events in patients with nephrotic syndrome secondary to membranous nephropathy. 2) To prospectively evaluate the role of low dose coumadin and antiplatelet therapy in the prevention of thrombotic complication of nephrotic syndrome secondary to membranous nephropathy. 3) To prospectively evaluate the benefit of anticoagulation in patients with documented thrombosis associated with the nephrotic syndrome of membranous nephropathy.

Technical Approach: This is a prospective, randomized study designed to evaluate the incidence of thromboembolic complications in patients with idiopathic membranous glomerulopathy, and the potential role for prophylactic low dose coumadin and antiplatelet therapy in the prevention of these complications.

Progress: Jun 95: No patients entered into the study. All information current. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-70 Status: Completed

Title: The Prevalence of Colonic Neoplasms in Patients with Known Breast Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ John Carrougner, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): CPT Karen Bowen, MC LTC Shailesh Kadakia, MC CPT Richard Shaffer, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 72  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the prevalence of colonic neoplasms in female patients with breast adenocarcinoma. We wish to determine if colonic neoplasms occur in greater frequency in patients with breast carcinoma than in a similarly matched control population. The information obtained from this study should be used to establish guidelines on colonoscopic surveillance in patients with breast cancer.

Technical Approach: Patient population will consist of all patients currently receiving care for breast adenocarcinoma in the oncology clinic at Brooke Army Medical Center. A letter will be sent to each patient soliciting participation. All participants will undergo colon screening to be accomplished by colonoscopy.

Progress: Jul 95: A total of 72 patients have been enrolled with the study completed. Dr. Carrougner has had permanent change of station to Madigan AMC and is compiling and analyzing the data and developing a publication.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-81 Status: Completed

Title: The Induction of the Alpha-Delta Sleep Anomaly and Fibromyalgia Symptoms in Normal Subjects: Correlations with Calorimetry and Insulin-like Growth Factor-1 (RENAMED)

Start date:	Estimated completion date:
Principal Investigator: MAJ Steven A. Older, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Rheumatology	Associate Investigator(s): LTC Daniel F. Battafarano, MC Sabri Derman, D.Sc I. Jon Russell, M.D., Ph.D. CPT Eugene Grady, MC
Key Words: fibromyalgia, sleep, Alpha-Delta, calorimetry, Insulin-Like Growth Factor1	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 10  
Total number of subjects enrolled to date: 25  
Periodic review date: Review results:

Objective(s): 1) To determine if artificial creation of Alpha-Delta sleep anomaly by selective deep sleep deprivation causes the development of fibromyalgia symptoms. 2) To determine if physical conditioning is protective against the development of fibromyalgia symptoms in sleep deprived individuals. 3) To analyze and compare serum levels of Insulin-like Growth Factor-1 in these individuals.

Technical Approach: Involves the evaluation of approximately 24 health civilian and active duty military volunteers between the ages of 18 and 40. These subjects, chosen in random order, will be studied in three separate groups: 1) Six subjects examined but not deprived of sleep (sham group); 2) Six subjects deprived of stage IV sleep (Stage IV group); 3) Twelve subjects deprived of both stages III and IV sleep (Stage III and IV group). Sleep deprived individuals will undergo five nights of monitoring in a sleep laboratory study. Their sleep will be undisturbed on nights #1 and #5 and interrupted by auditory stimulus on nights #2, #3, and #4 in order to achieve appropriate sleep stage deprivation. All subjects will be examined each morning and evening for the presence of tender points which will be measured quantitatively by dolorimetry. Urine and blood will be obtained for measurement of Insulin-like Growth Factor-1. All sleep deprivation subjects will undergo calorimetry testing within three weeks of their sleep study.



C-92-81 (continued)

Progress: Twenty-five subjects completed the study in 3 groups: Six in the control group, six in the stage 4 delta wave sleep interruption group (DWSI), and thirteen in the stage 3 + 4 DWSI. The major findings of the study were:

a. Increased sensitivity to pain and fibromyalgia symptoms occur following delta wave sleep interruption in a dose-dependent fashion. The effect, however, is not complete as less than two thirds of subjects undergoing aggressive DWSI (Stage 3 and 4) developed symptoms or an increase in pain sensitivity.

b. Sensitivity to pain in the morning is higher than in the evening in normal subjects. This difference is magnified following DWSI.

c. No evidence was found to suggest that aerobic fitness protects against DWSI-induced symptoms and sensitivity to pain. There is no direct evidence that aerobic deconditioning is a predisposing factor.

d. Serum levels of insulin-like growth factor 1, which were expected to decrease following deprivation of delta wave sleep, demonstrated no change after three sequential days of DWSI. It is therefore unlikely that insulin-like growth factor 1 plays a direct role in the development of myalgias associated with interrupted delta wave sleep.

Aug 95: Annual Review - Completion requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-85 Status: Ongoing

Title: Possible Hormone Manipulations in The Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date: 1 Sep 92	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To culture human T cells in a culture medium devoid of human or calf serum. This will allow full knowledge of what actually is necessary to culture T cells.

Technical Approach: Volunteers between ages 18-65 who are not pregnant will donate 10 ml of blood after signing a consent form. This 10 ml of blood will then undergo a process in order to culture normal human T cells. The 10 ml of whole blood will then be spun down to separate red blood cells from white blood cells. The buffy coat containing the white blood cells will then be removed and mononuclear leukocytes obtained via Ficoll-hypaque isopycnic centrifugation.

Progress: 7/95: Currently undertaking to see effect of Triac/Tetrac thyroid analogues upon HIV replication.  
 We are now repeating this experiment in larger groups with results to be published if once again, T cells are found to be independent. There are no complications/misadventures with all blood drawn only on subjects who also are part of the project.  
 Aug95: Dr. Thomason reports that a couple of presentations have been done on this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-94 Status: Completed

Title: Colon Carcinogenesis: Modulation by Dietary Intervention

Start date:	Estimated completion date:
Principal Investigator: COL Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 58  
Total number of subjects enrolled to date: 302  
Periodic review date: May of ea yr Review results:

Objective(s): 1) To assess the modulation of cellular proliferation in colonic crypts (a biomarker of colon cancer risk) by dietary supplementation with cellulose in patients identified at higher than normal risk of developing malignant colon cancer. 2) To determine if longer term dietary intervention (1 year or more) of the same supplements will result in a significant reduction in the recurrence of adenomatous polyps in the colon.

Technical Approach: Study will be conducted using a prospective randomized control trial. Two dependent variables will be measured: 1) proliferative zone height (PZH), the biomarker previously discussed in the Background and Significance Section and 2) recurrence rate of sporadic adenomatous polyps. The dependent variable, cellulose supplementation will be composed of three levels: 0, 15, and 25 grams/day above normal baseline intake level.

Progress: Aug 95: Since the study began and through 17 May 1995 a total of 302 patients have been enrolled in Phase I of the study. Of these 302 patients, 39 have been enrolled in the Phase II part of the study where they have been randomized to either no cellulose which includes 16 patients, to 15 gm cellulose which includes 14 patients, or 25gm cellulose to which 9 patients have been enrolled. Three parameters of cellular proliferation have been determined by immuno-staining for PCNA. The study is ongoing and attempts are continuing to enroll more patients in Phase I as well as Phase II.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-92-97

Status: Terminated

Title: Prospective Study of Clinical Efficacy of Two Formulations of Verapamil in Hypertensive Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ J. Grant Barr, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s): MAJ William Wright, MC
Key Words: Hypotension Calcium Channel Blocker	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether there are differences in efficacy, duration of action or side effects profiles of two different sustained release preparations of the calcium channel blocker. verapamil. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: Prior to beginning of experimental phase of the study, patients will have objective and subjective data collected. Patients will not be on any calcium channel blocker during this period however, all medications they are taking will be recorded. Physical examination will include recording of blood pressure and informed consent will be obtained.

Progress: Principal investigator has PCS'd. No one in Nephrology Service will take over this study. The Associate Investigator, LTC William Wright is TDY at another site. Study should be placed on hold until Dr. Wright's return and a determination is made as to whether he wishes to continue this study.  
 Annual Review 95: Termination requested.

# Detail Summary Sheet

Date: 1 Oct 95 Protocol Number: C-92-98 Status: Ongoing

Title: Possible Etiology for Euthyroid Sick Syndrome

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): Patients admitted to Brooke Army Medical Center (BAMC) who are seriously ill will potentially become candidates in the study. Judgement will be made by TRISS and APACHE III evaluation (an independent established method of objectively scoring patients) within 12 hours of admission to BAMC surgical or medical ICU by the staff physician involved in the study.

Technical Approach: Thyroid hormone levels and Triac/Tetrac levels will be tested in ICU patients at admission, as well as at 3 to 4 days and 2 weeks after admission. Subjects will vary as to their primary problem but all will be significantly ill. Analysis will be done to see if their clinical course and thyroid function tests correlate with Triac/Tetrac levels.

Progress: Dr. Merrill of clinical Investigation continues to attempt to isolate triac/tetrac.

# Detailed Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-01 Status: Ongoing

Title: Does Cholecystokinin (CCK) Prevent Gallbladder Sludge or Gallstone Formation in Patients Receiving Parenteral Nutrition? A Randomized Double-Blind Trial

Start date: 14 Oct 92	Estimated completion date:
Principal Investigator: Albert Fedalei, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Rashmikan B. Shah, M.D. Susan W. Wilson, M.S., R.D., L.P.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Oct of ea yr Review results: Continue

Objective(s): To compare the efficacy of cholecystokinin in preventing or reducing the incidence of gallbladder sludge and/or cholelithiasis formation in patients receiving total parenteral nutrition (TPN). The incidence of sludge and gallstones formation in the gallbladder will be determined in patients receiving either intravenous cholecystokinin or placebo.  
Technical Approach: All patients started on TPN will be invited to participate. The presence of gallbladder sludge and gallstone will be evaluated by standard ultrasound (US) technique. Appropriate images will be obtained for each study to record the findings for later review.

Progress: Oct 94: No input available.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-02 Status: Ongoing

Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Carl S. Wroblewski, M.D.	Facility: Darnall Army Hospital & Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: Ongoing

Objective(s): To determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Eligible patients will have a FFS performed by physicians in either the Internal Medicine or Gastroenterology Clinics after proper counselling. A colon cleansing preparation consisting of two Fleet's one hour prior to the examination will be administered.

Progress: As of 14 Sep 94, we are continuing to have patients complete the questionnaire prior to undergoing flexible sigmoidoscopy. The questionnaires are collected at the end of the examination and filed, the data has not been analyzed or reviewed. The study is ongoing and data will be analyzed or reviewed. The study is ongoing and data will be analyzed after about 12 to 24 months.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-03 Status: Ongoing

Title: 5-Fluorouracil Iontophoretic Therapy for Bowenoid Conditions

Start date: 26 Oct 92	Estimated completion date:
Principal Investigator: Martha L. McCollough, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Lawrence Anderson, M.D. William Grabski, M.D. Mark Welch, M.D.
Key Words: 5 Fluorouracil Bowen's Disease	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19

Total number of subjects enrolled to date: 27

Periodic review date: Oct of ea yr Review results:

Objective(s): To determine if the iontophoresis of 5-fluorouracil (5-FU) is an effective treatment for Bowen's disease and/or bowenoid actinic keratoses.

Technical Approach: As outlined in the protocol.

Progress: Oct 94: Annual Review no data available.



# Detail Summary Sheet

Date: 1 Oct 95 Protocol Number: C-93-05 Status: Ongoing

Title: A Comparison Study of the Prevention of Acute Aspirin Induced Gastroduodenal Injury with Omeprazole Versus Misoprostol

Start date: Mar 93	Estimated completion date: Jan 94
Principal Investigator: Timothy Pfanner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): R. Shaffer, M.D. J. Carrougner, M.D. S. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 24  
 Periodic review date: Mar of ea yr Review results: See below

Objective(s): To compare the effect of omeprazole versus misoprostol in the prevention of aspirin induced gastroduodenal mucosal damage in healthy volunteers.

Technical Approach: As outlined the study protocol.

Progress: Twenty-four patients have completed the study to date with Misoprostol preventing erosions and ulcerations vs placebo and Omeprazole showing no significant differences vs placebo. Approximately 40 more patients are required for completion of the study. Will require 1-2 years for completion; study ongoing.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-06 Status: Ongoing

Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Patients undergoing a FFS in either the Internal Medicine Clinic at Darnall Army Community Hospital or the Gastroenterology Clinic at BAMC will be eligible for the study. Detailed exclusion data, etc, in protocol.

Progress: Since the approval of the protocol in Oct 92, most patients undergoing FFS at GI Svc have been handed out a questionnaire which is collected soon after the FFS is completed. Questionnaires have not been analyzed at the present time. Many of the questions have not been appropriately answered by the patients and will require telephone calls in order to obtain detailed information concerning those questions. We continue to collect the questionnaires in the same fashion. As of 14 Sep 1994, we are continuing to have patients complete the questionnaire prior to undergoing flexible sigmoidoscopy. The questionnaires are collected at the end of the examination and filed, the data has not been analyzed or reviewed. The study is ongoing and data will be analyzed after about 12 to 24 months.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-08 Status: Ongoing

Title: Endosonoscopic Evaluation of Helicobacter Pylori Associated Gastritis

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: John G. Carrougher, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh Kadakia, M.D. Richard T. Shaffer, M.D. Michael D. Redwine, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date:  
Periodic review date: Nov of ea yr Review results: No significant findings

Objective(s): To determine if a sonographic pattern can be demonstrated in the gastric mucosa in patients with H. pylori associated gastritis. This information can help define the condition of H pylori gastritis and may assist the physician in the diagnostic difficulties seen with gastric wall abnormalities.

Technical Approach: The patient population will include all patients discovered to have H pylori infections as demonstrated by histology and/or urease test (clotest) during routine evaluation by the Gastroenterology Svc. The patients will then undergo endosonography followed by CT scan of the stomach wall. The EUS will be performed by the authors. The gastric wall will be examined using the UM3 endosonoscope from Olympus at frequencies of 7.5 and 15 MHZ. The gastric wall will be photographed in several areas during the EUS. CT scans will be photographed in several areas during the EUS. CT scans will be performed per routine of the radiology dept. Attempts will be made to assure adequate distention of the stomach during the CT scans and will be supervised by the radiologic staff. The radiology staff will be blinded to the results of the EUS. Gastric wall thickness will be measured by both modalities. All abnormal findings will be recorded. Patients may be collected from an preexisting protocol and will be studied prior to any antibiotic, or bismuth treatment.

Progress: No new subjects have been enrolled in the last 6 months with the protocol presently inactive and will likely be discontinued if no new subjects can be enrolled over the next 6 months.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-12 Status: Ongoing

Title: ASGE Survey: Anticoagulation and GI Endoscopy

Start date: 3 Nov 93	Estimated completion date:
Principal Investigator: Carlos E. Angueira, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2,500 surveys

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To survey the practices of randomly selected gastroenterologists throughout the country regarding patients on oral anticoagulation or antiplatelet therapy and the way in which these medications should be adjusted prior to and following gastrointestinal endoscopy.

Technical Approach: Questionnaires addressing the management of patient on oral anticoagulants, antiplatelet therapy and NSAIDs in the periendoscopy period and strategies in dosage adjustments of these agents will be sent to approximately 1200 randomly selected members of the American Society of Gastrointestinal Endoscopy (ASGE) as well as the directors of all the gastroenterology training programs throughout the country. Reminder letters will be sent 30 and 60 days after the questionnaires to ensure the highest rate of return possible. These questionnaires will then be analyzed with a statistical program to establish recommendations based on the consensus of the obtained responses.

Progress: Approximately 2500 surveys have been received. Data is being entered in computer for analysis.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-18 Status: Ongoing

Title: Monokine Induction in Patients Infected with Coccidioides Immitis

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA Chest Hosp; WHMC Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Rebecca Cox, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 14  
 Total number of subjects enrolled to date: 12: BAMC; 40: SASCH  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether infection with the fungus Coccidioides immitis causes an increased production of the monokines tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 beta (IL-1B), and interleukin 6 (IL-6) in patients with coccidioidomycosis. Specific aims include the comparison of the in vitro monokine responses of blood monocytes from six study groups: patients with acute (primary) pulmonary coccidioidomycosis; patients with chronic, progressive pulmonary coccidioidomycosis; patients with disseminated coccidioidomycosis; patients with previously diagnosed but inactive coccidioidomycosis; and healthy, spherulin skin-test positive and skin-test negative controls.

Technical Approach: Description of subjects/controls; criteria for inclusion/exclusion; experimental design/methods; data collection; statistical analysis and specifics outlined in protocol.

Progress: Monokine production assays are as published in the attached manuscript. Initial data for IFN- $\gamma$  production from selected cell lines (defined by BAMC FACS, Dr. Lopez/Mr. Ferguson) are seen in appendix 1. Despite excellent fractionation by the magnetic bead technique, a clean definition of IFN- $\gamma$  production from selected cell types has not yet been seen, although the numbers of adequate assays (CD experiments #8-10, with adequate con A control stimulation) are few. Our main difficulty in this line of investigation has been trade-offs between viable, bioactive cells and an adequate purification of same. Additional studies are underway. Basic

differences between the viabilities of live spherules in control (incubation with no cellular components) and total PBMC preparations have been adequately defined (appendix 2). However, clean separations between the abilities of fractionated cells in the killing of live spherules have not yet adequately been performed to our satisfaction. The main difficulties with this line of investigation have been, as per (2) above, the maintenance of cell viability after magnetic bead fractionation, as well as continuing suboptimal performance of both assay procedures currently used to determine spherule viability (CFU counts and labelled leucine incorporation). Despite these difficulties, additional studies are underway, as ultimately a definition of optimal killing of live spherules may have the greatest implications for therapeutic intervention. Cytokine mRNA determinations using RT-PCR of stimulated peripheral blood mononuclear cells isolated from normal donors have been optimized since these gels were run). Initial differences between cytokine patterns demonstrated by cells isolated from skin test-negative and -positive donors appear to be seen. The PCR to measure TNF mRNA has just been optimized (see TB report). With these assays for T-cell responses (esp. TH<sub>1</sub> and TH<sub>2</sub> responses) and monocyte/macrophage responses ready, studies are immediately pending on in situ lung cytokine profiles (one lung fragment destroyed by C. immitis, obtained from a State Chest hospital patient, is frozen and ready). No complications, misadventures, or adverse reactions have occurred as the result of these human studies.

\*Across the three participating institutions, 52 subjects were enrolled during the reporting period; 73 subjects have been enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-93-19      Status: Ongoing

Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

Start date: 9 Dec 92	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To assess the safety and efficacy of Anagrelide in patients suffering from thrombocythemia of various etiologies.

Technical Approach: Inclusion/exclusion criteria; concomitant medications; drug supplies; screening and initial treatment along with other specifics given in protocol.

Progress: One patient continues on study with no ill effects.  
 Mar 95: Reapproved - Annual Review.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-24 Status: Ongoing

Title: Comparison of the Effects of Nifedipine and Isradipine on Urinary Albumin Excretion and blood Pressure in Patients with Type Two Diabetes, Hypertension and Proteinuria

Start date: 4 Jan 93	Estimated completion date:
Principal Investigator: Kevin C. Abbott, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date:  
 Periodic review date: Jan of ea yr Review results:

Objective(s): This trial will evaluate the effects of isradipine and a sustained release formulation of nifedipine, Procardia XL<sup>TM</sup>, on arterial pressure and renal function. Renal function will be determined by twenty-four urine collections for creatinine clearance, fractional excretion of sodium, albumin and protein excretion.

Technical Approach: Subjects with type II diabetes with mild to moderate hypertension (defined in protocol) and urinary protein excretion of greater than one gram per twenty - four hours will be enrolled in the study. Age for eligibility will be 45 years or greater.

Progress: Principal Investigator has been deployed. Protocol status is unknown.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-26 Status: Ongoing

Title: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Anorexia Nervosa or Bulimia

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Neil Katz, M.D. Susan E. McManis, M.D., WHMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with anorexia nervosa or bulimia. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on empty into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying.

Technical approach: The importance of this project will be to demonstrate that erythromycin enhances gastric emptying in patients with anorexia and bulimia nervosa who have delayed gastric emptying. Since symptoms such as nausea, vomiting, abdominal pain, and early satiety may occur in these patients due to delayed gastric emptying, demonstration of faster gastric emptying after administration of erythromycin may provide therapeutic options in these patients.

Progress: Between 1 Dec 93 and 14 Sep 94 no additional patients have been entered in the study. The study is ongoing at the present time. The data analyzed is not different than previously reported since there are no additional patients in the study.

Nov 94: Gastric emptying is significantly improved in patients with anorexia nervosa and bulimia after IV erythromycin. The improvement in gastric emptying after IV erythromycin occurs without significant changes in serum motilin levels. (Kadakia)

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-28 Status: Completed

Title: Phase II Study of Brief Intravenous Adozelesin Infusion in Previously Untreated Extensive Small-Cell Lung Cancer

Start date: 29 Jan 93	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 1  
Periodic review date: Jan Review results: \_\_\_\_\_

Objective(s): To assess whether adozelesin given as a monthly intravenous infusion produces objective clinical responses in adult patients with previously untreated extensive small cell lung cancer. To determine the qualitative and quantitative toxicity and reversibility of toxicity of adozelesin administered in this fashion.

Technical Approach: This trial will be an open label, non-controlled, non-randomized, single dose, multiple-course, multicenter study. Further details including subject selection, treatment, and dosage included in protocol.

Progress: Accrual continues in this trial; treatment delays due to prolonged neutropenia have hindered the antineoplastic effects. A total of 16 patients have been accrued at all sites.

Jul 95: Completed as accrual goals have been met. Results are being analyzed and manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-33 Status: Ongoing

Title: S<sub>2</sub> Triggered MUGA for Assessment of Diastole by LTC Michael D. Lecce, MC

Start date: Oct 92	Estimated completion date:
Principal Investigator: Michael D. Lecce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D. Terry Bauch, M.D. James Heironimus, M.D. Neil Katz, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 13  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To establish the feasibility and potential clinical utility of Multi-Gated Blood Pool imaging using heart sounds as a trigger for image acquisition.

Technical Approach: The initial study will focus on: 1) The ability of this institution to use HSG for MUGA, 2) Compare the results of HSG Blood pool imaging to currently used technology and, 3) Establish institutional norms with the data acquired.

Progress: Several successful studies acquired; new sound transducer in use and accompanying results found. Presentation of results at national meeting anticipated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-37 Status: Ongoing

Title: Proposal for Research Model to Investigate Possible Hormone Manipulations in the Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date: 19 Mar 93	Estimated completion date: Spring 94
Principal Investigator: Kevin Carlin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Ron Kennedy Stephanie Anderson
Key Words:	Isidoro Chapa John W. Kelly, M.D. Gerald Merrill/Albert Thomason, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): HIV's entrance into a cell and subsequent pirating of the intracellular mechanisms bypasses the usual steps in cellular function. HIV's ability to infect cells and/or take over the functions of the cell, may be facilitated and/or inhibited by various hormone levels. If this was found to be true perhaps a hormone manipulation could be designed to enhance therapy.

Technical Approach: Specifics are given in protocol.

Progress: We are currently examining effect of Triac and Tetrac (thyroid analogues) upon HIV replication in vitro (cell culture and T cells).

# Detail Summary Sheet

Date: 1 Oct 95 Protocol Number: C-93-39 Status: Ongoing

Title: Relationship of Echocardiographic Doppler Indices of Diastolic Function to Severity of Cardiac Transplant Rejection.

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Sheri Y. Nottestad, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Nancy Khan, BSN Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22 patients/42 studies

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Nov ea yr Review results: Nov 93

Objective(s): To determine if serial changes in the echocardiographic Doppler A-Ar interval correlates with grades of cardiac transplant rejection.

Technical Approach: This study is a prospectively designed longitudinal study in which all cardiac transplant patients (n=25) on the transplant service at BAMC will be asked to participate. Following informed consent, 2-D doppler echocardiographic studies will be performed on patients undergoing routine right heart surveillance biopsies.

Progress: Data has been analyzed for all 42 studies performed to date on 22 patients. Early data analysis is encouraging for continuing the study. Presented at ACP meeting already.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-41 Status: Ongoing

Title: An evaluation of radionuclide angiography and echocardiography for assessment of doxorubicin induced ventricular dysfunction "

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Terry Jenkins, M.D. Neil Katz, M.D. James Heironimus, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 3

Periodic review date: Review results:

Objective(s): To determine the effects of doxorubicin on left ventricular diastolic function and to determine if radionuclide angiographic and/or echocardiographic parameters of diastolic dysfunction reliably precede doxorubicin-induced systolic dysfunction reliably precede doxorubicin-induced systolic dysfunction. this could allow the clinician to adjust or discontinue doxorubicin therapy before potentially irreversible loss of systolic function occurs.

Technical Approach: It is proposed that to test the hypothesis that, in patients receiving doxorubicin therapy, radionuclide angiographic and echocardiographic markers of left ventricular diastolic dysfunction reliably precede the loss of left ventricular systolic function. Specifics in protocol.

Progress: Enrollment by Hem/Onc slower than expected.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-43 Status: Ongoing

Title: Effects of the Nicotine Patch on Esophageal Motility

Start date: 24 Jan 93	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D. Richard T. Shaffer, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Jan of ea yr Review results:

Objective(s): To determine if the use of the nicotine patch has any effects on esophageal manometry studies.

Technical Approach: A total of 20 volunteers will be enrolled. These will consist of 20 healthy non-smoking adult volunteers. Age and sex will be noted for demographic data. Exclusion criteria will include pregnancy, chronic ETOH use, and any chronic medical conditions requiring medications that cannot be discontinued during the study period. Further details in protocol.

Progress: Investigator has PCSd. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-45 Status: Completed

Title: IND/IDE Trial of the Osteoport: A New Intraosseous Access Device

Start date: 27 Aug 92 Estimated completion date: May 94

Principal Investigator: Howard A. Burris, III, M.D. Facility: Brooke Army Medical Center, Texas

Department/Service: Medicine/Hematology-Oncology Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost: Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 4

Periodic review date: Jul of ea yr Review results: Completed

Objective(s): To determine the tolerance and clinical suitability of implanting the Osteoport™ in the iliac crest of patients who have failed at least one conventional venous access device. To determine the systemic bioavailability and the absorption rate profile of intraosseously (IO) administered morphine. To initiate an Experience of Use phase to determine longer term tolerance and estimated complication rates.

Technical Approach: Detailed specifics outlined in protocol.

Progress: Accrual to this clinical trial is complete and the results have been submitted to the FDA for a new device approval. Additional patients will be considered to further assess tolerability. A manuscript has been submitted to the New England Journal of Medicine.

Jul 95: Accrual goals have been met. Results are being analyzed and a manuscript is forthcoming.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-47 Status: Ongoing

Title: Validation of a Nonlinear Three Element Model for Estimating Stroke Volume and Aortic Flow Wave Form Morphology in Man

Start date: 24 Jan 93	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Karel H. Wesseling, Ph.D. John M. Karemaker, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To test the validity of at three-element nonlinear model for estimating aortic flow waveform morphology in man.

Technical Approach: This study will be a retrospective study in which flow waves derived from a three element non-linear Windkessel model<sup>2</sup> are compared to directly recorded electromagnetic flow/velocity waveforms. Details including data analysis included in protocol.

Progress: Progress on this project has been hampered by bioinstrumentation problems. Study is ongoing.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-49 Status: Ongoing

Title: Monokine Production in Patients Infected with Mycobacterium Tuberculosis and Human Immunodeficiency Virus

Start date: 23 Dec 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA State Chest Hosp; Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Greg Anders, M.D. Rebecca A. Cox, Ph.D. Kenneth Kemp, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 3 as of 1 Oct 94  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): The goal of this investigation is to determine if tuberculosis causes an increased production of the monokines tumor necrosis factor-alpha (TNF-a), interleukin-1B (IL-1), and interleukin-6 (IL-6) in persons infected with the human immunodeficiency virus (HIV). The specific aims will be to compare the in vitro monokine responses of purified blood monocytes, total peripherinuclear cells, and alveolar macrophages from four study groups: patients with concurrent Mycobacterium tuberculosis (MTB) and HIV infection; tuberculosis patients who are HIV-seronegative; patients with HIV infection without evidence of tuberculosis; and healthy, nontuberculous subjects who are seronegative for HIV.

Technical Approach: Description of subjects/controls, experimental design/methods, data collection and statistical analysis included in protocol.

Progress: Message amplification for the housekeeping gene, HPRT, and the cytokines IFN-y and IL-4 has been optimized; preliminary data obtained from PBMC obtained from the different donor groups is shown (appendix 1; sample gel, appendix 2). As can be seen, the production of IFNy was observed when PBMC from all groups were stimulated for 24 h with live BCG (a TB-specific organism). Although data suggests that IFN-y production is not the discriminator between successful or unsuccessful control of MTB disease, this cytokine may have been released from NK cells on exposure to BCG, and the

C-93-49 (continued)

response may be non-specific. However, a trend may have appeared demonstrating the lack of production of IL-4 (suggesting the absence of a suppressing TH2 response) from PBMC isolated from skin test-positive donors, as compared to more variable responses from patients or skin test-negative donors. Cytokine amplifications for other cytokines of interest have been performed and preliminary data is reported (appendices 3 and 4) on results obtained from cells (PBMC and BAL cells) from patients and normal donors. These assays have not yet been optimized to our satisfaction and no conclusions are suggested. BAL cells from one normal donor (the PI) and from two patients and lung samples from a lobectomy performed on a aTCID patient with a tuberculous lung, have been harvested and await message amplification. We are reluctant to perform these assays until the additional cytokine amplifications (IL-2, IL-10, IL-12, TNF-a, and TGF-b) have been perfected so as not to waste these valuable materials.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-52 Status: Ongoing

Title: Gemcitabine as Palliative Therapy in Patients with Progressive Carcinoma of the Pancreas

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To assess the clinical benefit of gemcitabine therapy in patients with progressive cancer of the pancreas as measured by significant improvement in pain, performance status, or weight change. Also, to measure time to progressive disease, survival, objective tumor response rates, duration of clinical benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in these patients.

Technical Approach: Detailed specifics outlined in protocol.

Progress: Several patients have experienced significant clinical benefit from this new agent for pancreatic cancer. Toxicity has been minimal to date.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-93-53

Status: Reopened

Title: Gemcitabine Versus 5-Fluorouracil in a Randomized Trial as First-Line Palliative Therapy in Patients with Carcinoma of the Pancreas

Start date: Dec 92

Estimated completion date:

Principal Investigator:  
Howard A. Burris, III, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Medicine/Hematology/Oncology

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To establish an advantage in clinical-benefit of gemcitabine over 5-fluorouracil (5-FU) in pain, performance status, or weight change. Also, to compare the treatment arms with respect to time to progressive disease, survival, objective tumor response rates, duration of clinical-benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in patients treated with gemcitabine and 5-FU.

Technical Approach: Detailed specifics outlined in protocol.

Progress: PI requested study be reopened.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-64 Status: Ongoing

Title: Effect of Omeprazole on Blood Alcohol Levels After Oral and Intravenous Ethanol

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Carole A. Buckner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Murray Francis, D.O. Shailesh Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: Mar of ea yr Review results:

Objective(s): To determine whether or not omeprazole has an effect on blood alcohol levels after oral and intravenous ethanol in normal, healthy volunteers.

Technical Approach: Twenty-two male subjects between the ages of 21 and 50 who are eligible for medical care at BAMC will be enrolled. They will be non-smokers and will be social drinkers who consume no more than two liters of beer a week or no more than one drink per day. They will not be on Antabuse or Flagyl, and must not have used any H<sub>2</sub>-receptor antagonists in the previous 2 weeks. Study will be conducted in four phases as outlined in protocol.

Progress: Data collection and analysis still in progress.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-65 Status: Ongoing

Title: Effect of Supportive Interventions on Patient Perception of Musculoskeletal Pain During Cardiac Catheterization

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Lois Miller, RN	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Sheri Y. Nottestad, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
 Total number of subjects enrolled to date: 18  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To test the effect of back and arm support interventions on the patients' perception of musculoskeletal pain during cardiac catheterization.

Technical Approach: There is a need to develop methods for reducing both the musculoskeletal pain and the consequent use of analgesics and narcotics to accomplish a level of comfort during cardiac catheterization. Details outlined in protocol.

Progress: No further patients enrolled-data results now under statistical analysis by LTC Richards, A.N.. Preliminary results show there is a difference in patient perception of musculoskeletal pain between central and group receiving compact measures.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-66 Status: Ongoing

Title: Myocardial Imaging Utilizing Positron Emission Tomography to Detect and Assess Coronary Artery Disease

Start date: 25 Mar 93	Estimated completion date: Unknown
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Landon Wellford, M.D. Neil Katz, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Mar of ea yr Review results:

Objective(s): Evaluation of the accuracy and utility of Positron Emission Tomography in the detection and assessment of coronary artery disease.

Technical Approach: Detailed specifics given in protocol.

Progress: Personnel at the PET Center has recently changed and we are now actively seeking subjects to enroll.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-69 Status: Completed

Title: Phase I Study of FCE 24517 in Adults with Advanced or Refractory Solid Tumors

Start date: 9 Apr 93	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 6  
 Periodic review date: Mar of ea yr Review results: Completed

Objective(s): To establish the maximally tolerated dose of FCE 24517 when given in divided doses intravenous daily x 3 every four weeks to adult patients with advanced and/or refractory solid tumors. To evaluate the acute toxicities and close limiting toxicity (DLT) of FCE 24517 in this patient population. To document any possible antitumor activity. Although a sufficiently sensitive, bioanalytical procedure for drug quantitation is not available at present, an attempt will be made to collect biofluid samples in order to explore possible concentration-response relationship.

Technical Approach: This is a dose finding study in patients with advanced and/or refractory tumors. The study will be open label and non-randomized. Based on preclinical toxicity data and Phase I Experience to date in europe, the initial starting dose of FCE 24517 will be 100 mcg/M<sub>2</sub> administered in three equally divided daily doses. The maximum tolerated dose level, based on single intravenous bolus injection, has not yet been determined based on European Phase I studies at doses up to and including 750 mcg/M<sup>2</sup>. Details included in protocol.

Progress: Accrual to this trial has been rapid and only 2 patients remain to be entered. The Dose Limiting Toxicity (DLT) myelosuppression. No objective tumor responses have been observed to date. Broad phase II testing is planned with this agent.

Mar 95: Completion requested at Annual Review.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: C-93-71                      Status: Completed

Title: A Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium avium Complex Disease in HIV Infected People

Start date: 1 Apr 93	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Apr of ea yr Review results: Completed

Objective(s): To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromized HIV infected patients with a CD4 count <100/ $\mu$ l.

Technical Approach: Selection of subjects, inclusion/exclusion criteria, study design, drug administration, etc. are outlined in protocol.

Progress: One patient continued on followup. No new patient entered on study.

4/95: Completed

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-73 Status: Completed

Title: A Phase II Study of Flutamide in Patients with Pancreatic Adenocarcinoma

Start date: 1 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the clinical benefit of flutamide in patients with advanced pancreatic adenocarcinoma as evidenced by improvement in pain control, performance status, or nutritional status.

Technical Approach: Eligibility criteria, descriptive factors, response criteria, etc., covered in protocol.

Progress: Accrual continues on this study. Evidence for clinical benefit has been observed. A total of 14 patients will be enrolled at which time the data will be analyzed regarding further accrual.

Jul 95: Completed as accrual goals have been met. Results are being analyzed and manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-74 Status: Completed

Title: A Phase I Dose Finding Clinical Trial to Evaluate the Safety and Pharmacokinetics of DMP 840 Given Daily for Five Consecutive Days (DX5) Every Four weeks in Cancer Patients with Refractory Solid Tumors

Start date: 6 May 93	Estimated completion date: 1 Jun 94
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words: DMP 840 Cancer Pharmacokinetics	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 9

Periodic review date: May Review results:

Objective(s): To determine the maximum tolerated dose (MTD) and the recommended dose (RD) for subsequent Phase II trials of DMP 840. To determine dose limiting toxicities (DLTLs) of DMP 840, including qualitative and quantitative toxicities, and to define their duration and reversibility. To evaluate the pharmacokinetics of intravenous DMP 840 administered on single daily doses for five consecutive days, as related to toxicity. To document any antitumor activity observed.

Technical Approach: Inclusion/exclusion criteria, study procedures, safety parameters, study medications and other specifics outlined in protocol.

Progress: Utilizing a brief-infusion schedule, a maximally tolerated dose of 14.0 mg/m<sup>2</sup> was found in minimally pre-treated patients. The dose-limiting toxicity was myelosuppression. Given the short initial half-life of the drug, patients are now being enrolled on a 120-hr infusion schedule. One patient at 10 mg/<sup>2</sup>/day experienced grade 4 thrombocytopenia, other patients are being enrolled to further define toxicity. No complete or partial remissions have been seen to date.

May/95: Study closed as accrual goals have been met. Results are being analyzed and manuscript will be forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-75 Status: Terminated

Title: Phase I Evaluation of API-395 Administered Intravenously Every 14 Days

Start date: 6 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine maximum tolerated dose (MTD) of API-395 and to assess cumulative toxicity of repetitive cycles of treatment every 14 days; to collect information about antitumor effects of API-395; and characterize the toxicities associated with API-395 treatment.

Technical Approach: Study population, treatment plan, toxicities to be monitored, dosage modifications and specifics outlined in protocol.

Progress: The opening of this study has been delayed because of the sale of API-395 (Oxaloplatin) from Axion to a French pharmaceutical firm. We anticipate this trial opening in late 1994, and will notify you accordingly prior to commencement.

Jul 95: Terminated due to drug company selling to another drug company.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-77 Status: Terminated

Title: High-Dose Chemotherapy and Total Body Irradiation with Autologous Stem Cell Support and Alpha Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis

Start date: 13 May 93	Estimated completion date:
Principal Investigator: W. Jeffrey Baker, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: May of ea yr Review results: Terminated

Due to significant toxicities and delayed engraftment experienced by the initial 5 patients placed on this protocol (one patient at BAMC and 4 at UTHSCSA) we have decided to close the protocol to further accrual. This protocol will be replaced by "High-Dose Chemotherapy with or without Total Body Irradiation with Autologous Stem Cell Support and Alpha Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis.

May 95: Annual Review - Termination requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-79 Status: Terminated

Title: The Effect of Bronchoalveolar Lavage Volume on the Diagnosis of Peripheral Primary Lung Cancer

Start date: 26 May 93	Estimated completion date: 1995
Principal Investigator: John F. Theroux, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): James E. Johnson, M.D. W. Kenneth Linville, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
Total number of subjects enrolled to date: 20  
Periodic review date: May of ea yr Review results:

Objective(s): To determine whether the use of a larger volume of brnchoalveolar lavage fluid increases the diagnostic yield of BAL cytology in peripheral, primary lung cancers.

Technical Approach: Patients undergoing FOB for evaluation of solitary lung masses will be asked to enroll. Of those that enroll, subjects will be included if they have no visible endobronchial disease during bronchoscopy and an ultimate diagnosis of cancer is made. Methods, data collection, statistical analysis, etc. included in protocol.

Progress: Twenty patients enrolled, however, 2 excluded due to benign diagnoses and one due to visible endobronchial disease. To date, the volume of BAL used has not affected the efficacy of this diagnostic procedure, as the cytology has been negative on every patient. Study will not be continued further and is terminated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-81 Status: Terminated

Title: Occurrence of Obstructive Sleep Apnea in Pregnant Women and an Evaluation of Its Impact on Fetal Outcome

Start date: 13 May 93	Estimated completion date: Jul 94
Principal Investigator: Daniel I. Loube, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease/Crit Care	Associate Investigator(s): Manuel L. Morales, M.D. Mark D. Peacock, M.D. Herman M. Blanton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 300

Total number of subjects enrolled to date: 300

Periodic review date: May of ea yr Review results:

Objective(s): To determine the incidence of obstructive sleep apnea (OSA) in pregnant women; and to evaluate the possible impact on OSA in pregnant women on fetal development and outcome.

Technical Approach: Statement of hypotheses, overview, experimental design, statistical analysis, etc, outlined in protocol.

Progress: Study indicates pregnant women snore significantly more than non-pregnant age matched women. This indicates increased upper airway resistance, which is epidemiologically related to OSA. However, we have only found four pregnant women with OSA, similar to what is expected in the normal population, but higher than previously reported for pregnancy (trend only). We have found no adverse effect upon fetal outcome related to self reported sleepiness or snoring. Study has been terminated and manuscript submitted.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-83 Status: Ongoing

Title: High-Dose Taxol, Cyclophosphamide, and Cisplatin (Taxol/CPA/cDDP) with Autologous Bone Marrow Support (ABMS) for Metastatic Breast Cancer

Start date: 10 Jun 93	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11  
 Total number of subjects enrolled to date: 11  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the toxicity, time to marrow reconstitution, response rate and time to treatment failure of high-dose combination chemotherapy with taxol, cyclophosphamide and cisplatin, followed by autologous marrow infusion in eligible patients with metastatic breast cancer. To provide a new drug in combination with other chemotherapeutic agents in management of individual patients with advanced breast cancer.

Technical Approach: Patient eligibility, descriptive factors, treatment plan, etc, outlined in protocol.

Progress: May 95 - Oct 93-Oct 94 = 8 patients  
 Oct 94-to date = 12 patients

By adding cyclosporin to the present taxol protocol - 20 patients, 12 were alive with addition of cyclosporin. Had 2 deaths (heart and liver failure). The calculated RR = 60% with 39% CR rate to date. Protocol is very well tolerated and the data has been presented at the BMT meeting in Arlington, TX. Also will be given in Jul 95 at SA Cancer Research Meeting.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-88 Status: Completed

Title: A Phase III Open-Label, Multicenter Trial of Actimmune Interferon Gamma-1b (rIFN-γ 1b) in Patients with Metastatic Renal Cell Carcinoma

Start date: 16 Jun 93	Estimated completion date: Apr 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the durable complete response rate (defined as a complete response of greater than 6 months' duration) of 100 μg of Actimmune administered subcutaneously once every 7 days to patients with metastatic renal cell carcinoma.

Technical Approach: Detailed specifics given in protocol.

Progress: Accrual is being completed nationally. A total of 14 patients have been enrolled in San Antonio with 2 objective responses noted. No toxicity problems to date.

Mar 95: Completion requested by PI.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-89 Status: Completed

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Ovarian Cancer

Start date: 16 Jun 93	Estimated completion date: Aug 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To assess the antitumor effect of five day (120-hr) infusion of intravenous ilmofofosine in patients with ovarian cancer; to assess the toxicity of ilmofofosine; to evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Accrual continues. Therapy has been well tolerated to date. An interim analysis will be performed on 20 patients.

Progress: Accrual continues. Therapy has been well tolerated to date. An interim analysis will be performed on 20 patients.

Mar 95: Completion requested at Annual Review.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-91 Status: Completed

Title: A Randomized, Double Blind, Placebo-Controlled Study of Parallel Design to Evaluate and Compare the Therapeutic Implant 5FU-e TI (5003) to its Placebo Vehicle when Administered to Patients with External Condylomata Acuminata

Start date: 30 Jun 93	Estimated completion date: 30 Jun 94
Principal Investigator: Dirk M. Elston, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Jeffrey Stiles, M.D. Norvell Coots, M.D.
Key Words:	Richard Vinson, M.D. Donna Corvette, M.D. Mark Peake, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 3  
Periodic review date: Annually/June Review results: Study completed

Objective(s): To evaluate the safety and efficacy of the Therapeutic Implant (5-FU-eTI 5003) with and without epinephrine, when administered in six weekly injections to male and female patients with external condylomata as compared to placebo gel (collagen). To describe the response rate, the time to recurrence and cumulative recurrence rate of condylomata in patients treated as outlined above. To evaluate the safety and efficacy of treatment in collagen skin test positive patients.

Technical Approach: Study design, inclusion/exclusion criteria, treatment plan and detailed specifics given in protocol.

Progress: May 95: Three patients completed the treatment phases of the study. One patient completed the follow-up phase, free of all warts. The second patients withdrew from the follow-up phase in order to seek treatment for non-target warts. (Non-target warts appeared during the treatment phase and were not eligible for treatment with the study drug). The non-target warts responded to other therapy. The third patient withdrew from the follow-up phase in order to seek treatment for non-target warts. Some non-target warts, as well as recurrences of target warts persist. the patient is still undergoing treatment at BAMC.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-92 Status: Completed

Title: A Phase I Trial of DS-4152 Administered as an Infusion Every 21 Days

Start date: 28 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose of DS-4152 administered as an infusion every 21 days. To determine the qualitative and quantitative toxicities of DS-4152 on this schedule. To determine the appropriate dose of DS-4152 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of DS-4152.

Technical Approach: Patient eligibility, treatment plan, pharmacokinetics, toxicity, and specifics given in protocol.

Progress: This trial is nearing completion with a Maximum Tolerated Dose (MTD) of 500 mg/m<sup>2</sup> determined. Additional patients are being accrued at an intermediate dose of 445 mg/m<sup>2</sup> to further assess tolerability. Preliminary results were presented at the European Organization for the Research and Treatment of Cancer (EORTC) meeting in Amsterdam, March 1994.

Mar 95: Completion requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-100 Status: Completed

Title: A Pilot Study of the Safety and Efficacy of an Intralesionally Administered Cisplatin Therapeutic Implant (MP 5010) in Patients with Superficially Accessible Tumors of Any History

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 6  
Periodic review date: Review results: Completed

Objective(s): To evaluate the safety and efficacy of the intratumorally administered CDDP TI (MP 5010) in patients with superficially accessible tumors of any history. To observe the tumor responses, and investigate the potential for efficacy and local disease control. To observe the duration of responses, and where biopsy is feasible and accepted by the patient, to observe the effects of intralesional MP 5010 on the histopathology of injected lesions that respond.

Technical Approach: Study design, patient selection criteria, treatment plan, doses, toxicity, etc, outlined in protocol.

Progress: This agent has been well tolerated with good clinical efficacy observed. Results were presented at the ASCO meeting in Dallas, May 94. A manuscript is underway. Several additional patients will be enrolled to assess tolerability.

Jul 95: Accrual goals have been met. Results are being analyzed and a manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-102 Status: Ongoing

Title: The Risk of Hemorrhage in Patients with Interstitial Lung Disease Undergoing Transbronchial Lung Biopsy

Start date: 1 Jul 93	Estimated completion date: Jun 96
Principal Investigator: Michael J. Morris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease & Crit Care	Associate Investigator(s): Mark D. Peacock, M.D. David Mego, M.D.
Key Words: Hemorrhage, interstitial lung disease, transbronchial biopsy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12 / 21

Total number of subjects enrolled to date: 25 / 45

Periodic review date: Jul ea yr Review results:

Objective(s): In a prospective manner this project will determine the incidence of clinically occult pulmonary hypertension (PH) in patients with interstitial lung disease (ILD). Subsequently, the rates of hemorrhage following transbronchial lung biopsy (TBBx) in patients with interstitial lung disease will be compared with regards to the presence or absence of clinically occult PH. We propose that PH detectable only by echocardiography does not increase the risk of hemorrhage during TBBx.

Technical Approach: The hypothesis to be tested is that PH, that is not clinically evident by physical exam and radiographic evaluation, but detectable by echocardiography does not cause increased hemorrhagic complications from transbronchial biopsies. Further specifics in protocol.

Progress: Jun 95: 45 patients have been enrolled into study. There have been no bleeding complications (all patients have had minimal bleeding), although several patients have had moderate increases in pulmonary systolic pressures without increased bleeding.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-104 Status: Ongoing

Title: Phase I Trial of VP16 + AMGEN rG-CSF in Patients with Advanced Malignancies

Start date: 30 Jul 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. David A. Rinaldi, M.D. Patrick Cobb, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To determine the maximally tolerated dose and toxicities of VP16 when combined with r-G-CSF in patients with advanced malignancies.  
To determine which schedule of administration of r-G-CSF and VP16 is superior in ameliorating toxicity while maximizing potential synergy of the two agents.  
To determine the recommended dose and schedule of VP16 + r-G-CSF to be used in phase II trials.  
To document any responses that may occur with this combination.

Technical Approach: Design/methods, subject population, recruitment and other specifics outlined in protocol.

Progress: This protocol has not commenced accrual as an IND# was pending. The # has now been issued by the FDA and arrangements are being made with the sponsor to open the study. Notification will be made prior to enrolling patients.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-115 Status: Terminated

Title: Obstructive Sleep Apnea and Silent Myocardial Ischemia in Post-Myocardial Infarction Patients: frequency, temporal relationship, and response to nasal continuous positive airway pressure (nCPAP) therapy

Start date: Aug 93	Estimated completion date: Aug 94
Principal Investigator: Terry D. Bauch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Nancy A. Khan, BSN Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 4  
Periodic review date: Review results:

Objective(s): 1) Identify obstructive sleep apnea (OSA) in post-myocardial infarction(MI) patients with known risk factors for OSA. 2) Investigate the frequency of, and temporal relationship between episodes of OSA and Silent Myocardial Ischemia (SMI) in post-MI patients. 3) Determine the effect of nCPAP treatment of OSA upon SMI in post-MI patients.

Technical Approach: Subjects, methods, data collection, statistical analysis, etc., outlined in protocol.

Progress: No progress made. No adverse effects. Study terminated prior to completion - unable to identify efficient size patient population.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-117 Status: Ongoing

Title: A Phase II Study of Gemcitabine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: Aug 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: Jun of ea yr Review results: Continue

Objective(s): To assess the clinical-benefit of intravenous gemcitabine in patients with hormone-refractory prostate cancer (HPRC) as measured by Karnofsky Performance Status (KPS), and pain palliation.

Technical Approach: Investigational plan, study population, dosage & administration, concomitant therapy and other specifics covered in protocol.

Progress: May 95: A total of 14 patients have been enrolled at all sites. The therapy has been very well tolerated. Several patients have benefitted from improvement in pain and performance status. Accrual continues to a total of 20 patients.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-122 Status: Ongoing

Title: A Single Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

Start date: Oct 93	Estimated completion date:
Principal Investigator: Leo A. Conger, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Dirk M.Elston, M.D. Mark Peake, M.D. Rick Keller, M.D.
Key Words: Acne Retin-A	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 32  
Periodic review date: Oct of ea yr Review results:

Objective(s): To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

Technical Approach: At present, the standard treatment with Retin-A involves applying the cream each night to the entire affected area. This method has been generally successful in reducing the number of acne lesions, especially open and closed comedones. Irritation is a common side effect of nightly Retin-A therapy. Preliminary observations suggest that less frequent applications may still be effective therapy, with less irritation and lower cost. Further specifics outlined in protocol.

Progress: Patient recruitment has been extremely slow. Since Dr. Biediger was transferred to Ft Hood, I have become the principal investigator here at BAMC. Plan is to have patient recruitment from both Ft Sam and Ft Hood.

Oct 95: Recruiting continues to be dismal, little to no progress since last years' review.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-124 Status: Terminated

Title: The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction

Start date: 14 Sep 93	Estimated completion date:
Principal Investigator: James K. Gilman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: N/A	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: N/A Review results: N/A

Objective(s): To determine whether d-sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction (resting LV ejection fraction < 40%) and CHD.

To compare the safety and tolerance of d-sotalol with placebo when administered long-term to patients with LV dysfunction (resting LV ejection fraction < 40%) and CHD.

Technical Approach: Study design/eligibility, safety and specifics outlined in protocol.

Progress: Three patients enrolled. No adverse events. Study proceeding well.

Nov 94: Terminated at request of drug company.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-125 Status: Ongoing

Title: Endosonics PTCA Balloon Catheter: Eagle

Start date: 14 Sep 93	Estimated completion date:
Principal Investigator: William T. Wright, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To evaluate the safety and efficacy of the device. In addition to achieving this objective, the study will supplement the growing body of knowledge concerning the procedure, assisting physicians with some of its technical aspects, aiding them in selecting candidates most likely to benefit from the procedure, and providing them with comprehensive data to use in comparing this form of therapy for coronary artery disease to the presently available alternatives.

Technical Approach: Patient selection, risk analysis and specifics are outlined in protocol.

Progress: We were notified by Endosonics that there is a problem with the balloon. They requested that this study be placed on hold status.  
Sep 95: Status remains the same.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-129 Status: Ongoing

Title: A Phase II Study of MGBG in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 21 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA; CTRCofSA; & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Suzanne M. Fields Daniel D. Von Hoff, M.D. Geoffrey Weiss, M.D. John R. Eckardt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Mar of ea yr Review results: Continue

Objective(s): To assess the clinical benefit of intravenous MGBG in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation.  
To determine the objective response rate of intravenous MGBG in those patients with HRPC and measurable disease.  
To evaluate the qualitative and quantitative toxicities of intravenous MGBG in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration, etc, covered in protocol.

Progress: Accrual of patients temporarily halted due to toxicity (mucositis). Enrollment has resumed on a modified dose schedule with pharmacokinetics (PK) being collected.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-133 Status: Ongoing

Title: Phase II Trial of RP 56976 in Patients with Cholangiocarcinoma

Start date: 24 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Patrick W. Cobb, M.D. John R. Eckardt, M.D. Suzanne Fields, Pharm.D. Stephen Kalter, M.D. John G. Kuhn, Pharm.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Aug of ea yr Review results: Continue

Objective(s): To assess whether taxotere given as an every three week intravenous infusion procedures objective clinical responses in patients with cholangiocarcinoma.  
 To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous taxotere.

Technical Approach: Design, dose regimen, number and selection of patients, and other specifics are outlined in protocol.

Progress: Prioritization of resources has led the sponsor to not open this study.

Aug 95: A total of 15 patients have been enrolled (5 at other sites in San Antonio, 10 at MD Anderson in Houston) with 1 objective response. No unexpected problems to date. Accrual will continue to a total of 20 patients.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-02 Status: Completed

Title: Twenty-four Hour Heart Rate Variability and Intravascular Volume: Are They Abnormal in Young Active Duty Soldiers with Tilt Induced Syncope?

Start date: 18 Oct 93	Estimated completion date:
Principal Investigator: Robert Rudolphi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Bernie Rubal, Ph.D. LuAnn Wellford, M.D.
Key Words: Tilt Induced Syncope, Heart rate variability (HRV)	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: About 10  
Periodic review date: Oct of ea yr Review results: Completed

Objective(s): This investigation hopes to definitively determine if heart rate variability (HRV), specifically the parasympathetic component, is greater in young people with tilt induced neurally mediated syncope (NMS). Also, plasma volume prior to tilt testing will be assessed to determine if NMS patients have lower baseline intravascular volume compared to normal controls.

Technical Approach: Patient criteria, heart rate variability, tilt test, plasma volume, statistical analysis and further details included in protocol.

Progress: Oct 95: Dr. Gilman reports that this was a favorable study and a paper on it was presented at the ACP meeting in town.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-04 Status: Ongoing

Title: Growth of Human Basal Cell Carcinoma Cells in Defined Medium and Study of Their Growth and Immunologic Characteristics

Start date: 20 Oct 93	Estimated completion date:
Principal Investigator: Lawrence Anderson, M.D.	Facility: Wilford Hall AFMC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): William J. Grabski, M.D. Ronald E. Grimwood, M.D.
Key Words: keratinocyte growth medium, epidermal growth factor, basal cell carcinoma, tissue culture	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None
Number of subjects enrolled during reporting period: 6	
Total number of subjects enrolled to date: 6	
Periodic review date: Review results:	

Objective(s): The growth and study of basal cell carcinoma cells in culture.

Technical Approach: The defined medium for basal cell growth will consist of keratinocyte growth medium complete with epidermal growth factor, bovine pituitary extract, insulin, hydrocortisone and anti-microbial agents. This is a modified MCDB 153 formulation that is serum free and comes augmented with growth factors as stated above. Tissue for culture will be obtained from the Department of Dermatology at Wilford Hall MC and BAMC which will have been collected during a normal surgical procedure and will not subject the patient to any additional procedures. Further specifics outlined in protocol.

Progress: Preliminary growth of basal cell carcinoma in a defined medium has been successful. Success was obtained with the morphea type of basal cell carcinoma, whereas the results with the other subtypes of tumor were less encouraging. A collagen matrix preparation appears to be the best tissue culture medium. Unfortunately, the cells did not successfully pass in subsequent culture. Continued study of determining the best culturing techniques is planned.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-08 Status: Ongoing

Title: Elimination of Extrachromosomal DNA from Ovarian Cancer Patients' Tumors with Hydroxyurea Treatment

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Extrachromosomal DNA, Hydroxyurea, refractory ovarian cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if hydroxyurea can decrease the amount of extrachromosomal DNA in patients' ovarian cancer cells. To determine if hydroxyurea can decrease the number of ovarian cancer cells in patients' malignant ascites. To determine the amount of transport of hydroxyurea into malignant ascites of patients with ovarian cancer. To determine if hydroxyurea induces responses in patients with advanced refractory ovarian cancer.

Technical Approach: Patient eligibility criteria, descriptive factors, treatment plan and detailed specifics are outlined in protocol.

Progress: Accrual has been slow but preliminary results are encouraging. Ascites has been ameliorated and extrachromosomal LDNA counts reduced with the use of hydrea.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-19 Status: Ongoing

Title: Time-Frequency Analysis of Phonocardiograms: A Study of Prosthetic Heart Valve Sounds

Start date: Dec 93	Estimated completion date:
Principal Investigator: J. Mark Moody, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): James R. Bulgrin, BS-EE Bernard J. Rubal, Ph.D. Terry D. Bauch, M.D. T. E. Posch, MS-EE
Key Words: Phonocardiograms (PCG), Prosthetic Heart valve	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: Info as of 3 Dec 93

Total number of subjects enrolled to date: Over 5,000 = 6,609

Periodic review date: Aug of ea yr Review results: See below

Objective(s): To evaluate an inexpensive, non-invasive method of analyzing phonocardiograms (PCGs) in order to longitudinally assess evolving structural and physiologic problems associated with implanted heart valve prostheses.

Technical Approach: This is a descriptive study intended to characterize the time-frequency distributions, via several analytical techniques, of PCGs from as many patients with prosthetic heart valves as possible, and following these patients over a significantly long interval. Further details in protocol.

Progress: Still in processing of establishing technology to acquire, analyze and display signals: We have acquired data on two patients, neither satisfactory.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-94-22      Status: Ongoing

Title: Time-Frequency Analysis of ECG in Patients Post-Myocardial Infarction and at Risk for Sudden Death

Start date: Nov 93	Estimated completion date:
Principal Investigator: Thien M. Do, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Bernard J. Rubal, Ph.D. James R. Bulgrin, BSEE T. E. Posch, MS-EE, Hughes Aircraft
Key Words: Post-myocardial infarction, inducible ventricular tachycardia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
Total number of subjects enrolled to date: 20  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the clinical utility of time-frequency analysis of the ECGs in sudden death survivors and patients post myocardial infarction and with inducible ventricular tachycardia.

Technical Approach: Inclusion/exclusion criteria, methods for obtaining TFD and signal averaged ECGs, etc. covered in protocol.

Progress: Sent to California for analysis. Awaiting new software in order to do analysis here.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-23 Status: Ongoing

Title: A Phase I Study of AM-285 Administered Via the Intraperitoneal Route in Patients with Intraperitoneal Predominantly Tumoral Disease

Start date: Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words: Intraperitoneal route, pharmacokinetic profile	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the safety and tolerance of AM-285 at doses ranging from 10 to 150 mg/kg administered by the intraperitoneal route. To determine the pharmacokinetic profile of AM-285 when administered via this route/schedule.

Technical Approach: Patient selection, study synopsis (treatment program), and other specifics included in protocol.

Progress: This study is on hold pending deliberations with the sponsor. It is unclear if intraperitoneal administration is a worthwhile route to pursue.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-24 Status: Ongoing

Title: A Phase I Trial of LY231514 Administered as a Bolus Given Intravenously Every 21 Days

Start date: Sep 93	Estimated completion date: 1 Oct 94
Principal Investigator: David A. Rinaldi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Daniel D. Von Hoff, M.D. Howard Burris, III, M.D. Timothy J. O'Rourke Patrick Cobb, M.D. Enriquez Perez, M.D., et al
Key Words: bolus infusion, pharmacokinetics/pharmacodynamics LY231514, cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 10  
Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose of LY231514 administered as a bolus infusion given every 21 days. To determine the qualitative and quantitative toxicities of LY231514 on this schedule. To determine the recommended dose of LY231514 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of LY231514. To collect information about the antitumor effects of LY231514.

Technical Approach: Study population/criteria, dosage administration, efficacy criteria and detailed specifics outlined in protocol.

Progress: Eight patients have been treated on this protocol at BAMC. The dosages have been escalated from 50 mg/m<sup>2</sup> to 700 mg/m<sup>2</sup>. Currently patients are being accrued at 60 mg/m<sup>2</sup>, which is anticipated to be the recommended phase II dose. The dose limiting toxicities are neutropenia, thrombocytopenia, mucositis and malaise at the 700 mg/m<sup>2</sup> dose level. Pharmacokinetics have been obtained in all patients. There have been no major antitumor responses to date, however, one patient with advanced colon cancer exhibited a minor response.

Aug 95: Ten patients from BAMC have been enrolled on the protocols, 2 since the last report to the IRB in Sep 94. No further patient accrual is planned. No BAMC patients are currently on study. The maximally tolerated dose and planned dose for phase II clinical trials is 600 mg/m<sup>2</sup>. The dose-limiting toxicities are neutropenia, thrombocytopenia and fatigue. Pharmacokinetics have been obtained in all patients and demonstrated a half-life of approximately 4 hours. Seventy-eight percent of the compound is excreted unchanged in the urine. There have been 4 partial responses, 2 each in patients with advanced colorectal and pancreatic cancer.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-25 Status: Ongoing

Title: A Phase I/II Dose-Escalating Study of Intravenously Administered Tirapazamine (WIN 59075) in Combination with Cisplatin, in Patients with Non-Small Cell Lung Cancer

Start date: Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: CTRC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Gladys I. Rodriguez, M.D.
Key Words: Tirapazimine, Cisplatin, maximum tolerated dose (MTD)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Sep of ea yr Review results:

Objective(s): To determine the safety and side effects of tirapazamine, when administered IV in combination with cisplatin, by monitoring patients for adverse effects through clinical observations and laboratory parameters. To determine the pharmacokinetics of tirapazamine and cisplatin, when administered IV in this combination with cisplatin, through periodic sampling of the patients' body fluids. To estimate the maximum tolerated dose (MTD) of tirapazamine, when administered IV in combination with cisplatin, by evaluating all therapy related adverse events. To assess the effects of tirapazamine, when administered IV in combination with cisplatin, on tumor tissues through tumor measurements.

Technical Approach: Study design, inclusion/exclusion criteria, study plan, dosing procedure and specifics outlined in protocol.

Progress: Accrual has gone well and numerous objective responses have been observed. The treatment has been well tolerated except for delayed nausea and vomiting and some mild electrolyte abnormalities. A Phase II trial with this combination will be conducted once the Maximum Tolerated Dose (MTD) has been established.

Aug 95: The Phase I trial has been completed with excellent activity observed. Toxicities included elevated creatines, muscle cramping, electrolyte abnormalities and myelosuppression. A Phase II trial has begun at the highest tolerable dose.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-26 Status: Completed

Title: A Rising Dose-Level, Safety Tolerability and Pharmacokinetic Phase I Study of GII47211 Administered Daily by Injection for Five (5) Consecutive Days to Patients with Cancer

Start date: Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: CTRC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D.
Key Words: Rising dose-level, safety tolerability, anti-tumor activity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Review results:

Objective(s): 1. Evaluate safety and tolerability of GII47211 within the dose range of 0.3mg/M<sup>2</sup>/day to the maximum tolerable dose when administered by daily injection for five consecutive days; 2. Evaluate the pharmacokinetics of GII47211 in patients with cancer; 3. Evaluate the dose-related tolerability of GII47211, with emphasis on correlating hematologic effect with GII47211 plasma concentrations; 4. Assess the pharmacodynamics of GII47211 with hematologic toxicity as a dynamic end point and; 5. Assess, in a preliminary manner, early anti-tumor activity.

Technical Approach: Patient selection, study procedure, data collection/analysis and detailed specifics given in protocol.

Progress: This phase I trial nears completion. Toxicities have centered around myelosuppression including both neutropenia and thrombocytopenia; non-hematologic toxicity has been mild. No antitumor activity observed to date.

Mar 95: Completed



# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-27 Status: Ongoing

Title: Percutaneous Transluminal Coronary Angioplasty Versus Coronary Stenting of De Novo Saphenous Vein Bypass Grafts

Start date: 30 Dec 93	Estimated completion date:
Principal Investigator: William T. Wright, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D.
Key Words: De Novo, saphenous vein bypass grafts, balloon angioplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: Dec of ea yr Review results:

Objective(s): The placement of expandable stents in saphenous vein grafts has shown initial promising results in terms of lower rates of restenosis compared with balloon angioplasty. This is a multicenter, randomized study designed to further examine this subject. Patients with de novo stenoses of saphenous vein grafts will be assigned randomly to either routine angioplasty or the placement of a coronary stent, (supplied by Johnson and Johnson Interventional Systems, Co). Restenosis will be evaluated by routine clinical follow-up, including exercise testing and repeat angiography when indicated. Analysis of angiography and data will be performed by a core lab. BAMC will enroll 15-30 patients, in conjunction with the Univ of Texas Health Science Center at San Antonio Cardiology Service.

Technical Approach: Study population, inclusion/exclusion criteria, materials/methods and further specifics outlined in protocol.

Progress: Total enrollment = 15/total BAMC enrollment = 6:  
1 Death unrelated to stent  
2 of 3 stent patients restenosed  
3 of 3 PTCA patients free of symptoms continuing to enroll patients who meet criteria; monitoring clinical followup.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-34 Status: Ongoing

Title: Comparison of Fluorescent Bronchoscopy to White-Light Bronchoscopy in Detecting Lung Carcinoma

Start date: 21 Jan 94	Estimated completion date:
Principal Investigator: Gregg T. Anders, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease/Crit Care	Associate Investigator(s): H. M. Blanton, M.D.
Key Words: Fluorescent Bronchoscopy, White-light bronchoscopy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To determine any statistically significant increase in lung cancer diagnosis using fluorescent bronchoscopy as compared to white-light bronchoscopy performed on the same period. Patients will be selected from three groups for whom the medical literature has suggested a higher than usual rate of occurrence (or, in some cases, recurrence) of bronchogenic carcinoma-- patients in whom lung cancer has been resected; patients diagnosed with head and neck cancer; and patients who smoke more than two packs of cigarettes daily.

Technical Approach: Patients will serve as their own controls via the white-light bronchoscopy. They will be selected from one of the following groups: 1. Patients with Stage I resected lung cancer without evidence of metastasis, referred from the Thoracic Surgery service or the Medical Oncology Clinic to the Pulmonary clinic, BAMC; 2. Patients with surgically resected head and neck cancer without evidence of metastasis at the time of initial diagnosis, referred from the Otolaryngology Clinic; 3. Patients referred to BAMC Pulmonary Service of the Smoking Cessation Clinic who are currently smoking more than two packs of cigarettes per day with symptoms of cough or dyspnea. Inclusion/exclusion criteria details included in protocol.

Progress: One patient has been enrolled thus far - equipment was not on-line prior to 15 Sep 94.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-36 Status: Ongoing

Title: A Phase I Trial of Losoxantrone in Combination with Paclitaxel in Patients with Refractory Malignancies

Start date: 24 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: VA, CTCR, St. Luke's Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Howard Burris, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Losoxantrone, Paclitaxel, Dose limiting toxicities (DLTs), qualitative/quantitative toxicities	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 4  
Periodic review date: Aug of ea yr Review results:

Objective(s): 1. To determine the maximum tolerated dose (MTD) and the recommended dose (RD) for subsequent Phase II trials of losoxantrone in combination with paclitaxel. 2. To determine the dose limiting toxicities (DLTs) of losoxantrone in combination with paclitaxel, including qualitative and quantitative toxicities, and to define their duration and reversibility. 3. To evaluate the pharmacokinetics of losoxantrone and paclitaxel when given in combination. 4. To evaluate the antitumor activity of losoxantrone plus paclitaxel. Study design, duration, study population, medications, etc., outlined in protocol.

Technical Approach: Approximately six months will elapse from the enrollment of the first patient until the enrollment of the last patient. Enrollment will continue until the maximum tolerated dose is identified.

Progress: The initial dose of losoxantrone 40mg/m<sup>2</sup> and paclitaxel 135 mg/m<sup>2</sup> given over 24 and 3 hours had unacceptable neutropenia as its toxicity. G-CSF was added to the regimen for prevention of neutropenic fevers. Patients then tolerated the dose level well and further dose escalations are ongoing.  
Aug 94: No report furnished.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-37 Status: Ongoing

Title: The Effect of h Corticotrophin-Releasing Factor on Peritumoral Brain Edema, A Pilot Study

Start date: 25 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: h-Corticotrophin-Releasing Factor, Peritumoral Brain Edema	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: Jul of ea yr Review results: Continue

Objective(s): 1. To evaluate the tolerability of hcorticotropin-releasing factor administered intravenously in ascending doses to patients with peritumoral brain edema. 2. To determine if hcorticotropin-releasing factor produces any reduction in peritumoral brain edema as determined by magnetic resonance imaging.

Technical Approach: Materials/methods, study population, study design, study plan and management, etc, outlined in protocol.

Progress: This trial has recently opened with 5 patients enrolled to date. No toxicity and good efficacy has been observed in this first cohort.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-38 Status: Ongoing

Title: Phase 2 Double-Blind, Randomized Study of Recombinant Human Interleukin 11 (NEUMEGA rhIL-11 Growth Factor) at Doses of 25 and 50 mcg/kg/d vs Placebo in Adult Cancer Patients with Severe Thrombocytopenia Due to Chemotherapy

Start date: 27 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: VA, CTTC, St Luke's Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: rhIL-11 Growth Factor, Placebo, Thrombocytopenia, ameliorating	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the activity of two doses (25 and 50 mcg/kg/d) of recombinant human interleukin 11 (NEUMEGA™ rhIL-11 Growth Factor) with a placebo in ameliorating severe chemotherapy-induced thrombocytopenia in cancer patients receiving a variety of chemotherapy regimens and to gain additional information regarding the safety of rhIL-11 administration at the specified doses. Also to assess whether IL-11 antibodies are produced and to measure IL-11 serum levels.

Technical Approach: Design, eligibility, treatment plan, adverse experiences, statistical analysis, etc, outlined in protocol.

Progress: Accrual has gone poorly at all sites. A very specific and difficult to find population is being studied. Attempts at enhancing accrual are being made.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-39 Status: Ongoing

Title: Phase I Clinical and Pharmacokinetic Evaluation of LY 295501  
Administered Orally on a Weekly Schedule in Patients with Metastatic Cancer

Start date: 27 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Metastatic, Maximum tolerated dose, anti-tumor effects	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: Jan of ea yr Review results: Continue

Objective(s): Primary objective of this study is to determine the maximum tolerated dose (MTD) of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer. Secondary objectives are to determine the qualitative and quantitative toxicities of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer, to determine the recommended dose for LY295501 to be used for initial therapeutic trials, to determine the basic pharmacokinetics of LY295501 by study of plasma and urinary levels of the agent in humans, and to collect information about the antitumor effects of LY295501.

Technical Approach: Study design, control, population, patient assignment, dosage administration, etc., outlined in protocol.

Progress: Accrual has gone well with minimal toxicity observed to date.  
Dec 94: PI requested study be put on hold but remain open at request of drug company.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-42 Status: Ongoing

Title: A Phase I Trial of Paclitaxel; (IVX-T-101) Administered as a Three-Hour Infusion in Patients with Refractory Non-Small Cell Lung Cancer

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D.
Key Words: Paclitaxel, non-small cell	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Nov of ea yr Review results:

Objective(s): 1. To determine the maximal tolerated dose of paclitaxel given as a 3-hour infusion every 21 days. 2. To determine the qualitative and quantitative toxicities of paclitaxel given as a 3-hour infusion every 21 days. 3. To characterize the pharmacokinetics of paclitaxel administered as a 3-hour infusion. 4. To determine the recommended dose of paclitaxel given as a 3-hour infusion every 21 days to be used in Phase II trials. 5. To collect information about the antitumor effects of paclitaxel in patients with Non-Small Cell Lung Cancer.

Technical Approach: Drug info, eligibility criteria, treatment plan, pharmacokinetics, etc., outlined in protocol.

Progress: Due to problems in drug manufacturing, this trial has not accrued patients. We expect to begin enrollment within the next few months.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-43 Status: Ongoing

Title: Comparison of Newer Doppler-Echocardiographic Methods for the Quantification of Mitral Regurgitation

Start date: 4 Feb 94	Estimated completion date:
Principal Investigator: Jerry D. Champ, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words: Mitral regurgitant volume, control velocity,	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16  
Total number of subjects enrolled to date: 16  
Periodic review date: Feb of ea yr Review results:

Objective(s): To compare the mitral regurgitant volume as determined by three quantitative Doppler techniques -- 1) a volumetric method utilizing Doppler-derived stroke volume in the left ventricular outflow tract and mitral annulus; 2) a technique involving color flow imaging of the flow convergence region; 3) a new method involving the product of the mitral regurgitant color flow jet area and the mitral regurgitant time velocity integral.

Technical Approach: The quantification of mitral regurgitation has been a long-standing problem of some clinical importance. Difficulties in quantifying the regurgitant flow continue despite the advent of Doppler echocardiographic methods for measuring the severity of mitral regurgitation. Several newer techniques have been advanced in the literature addressing this problem. This study compares the accuracy and ease of use of these techniques for calculating regurgitant volume with a volumetric Doppler method in a clinical setting.

Progress: Preliminary statistical analysis on 11 patients reveals a correlation coefficient for the area method of  $r=0.83$  and that for the flow convergence method of  $r=0.49$ .



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-44 Status: Ongoing

Title: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Billroth I or Billroth II Anastomosis

Start date: 1 Feb 94	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Neil Katz, M.D. Rashmikan Shah, M.D. Vimal Sodhi, M.D.
Key Words: Erythromycin, Billroth I, Billroth II, anastomosis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with Billroth I and Billroth II anastomosis. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on entry into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying. In addition, serum levels of motilin will be obtained during the baseline gastric emptying study and the gastric emptying study after intravenous erythromycin administration.

Technical Approach: All symptomatic adult patients (older than 18 years) who have had previous ulcer surgery wherein billroth I or Billroth II anastomosis was performed will be invited to participate in the study. These patients will be evaluated by the staff principal investigator. Patient inclusion/exclusion criteria outlined in protocol. Detailed specifics are outlined in protocol.

Progress: Since the approval date of 1 Feb 94 and 14 Sep 94 no patients have been enrolled in this study. We are currently in the process of involving an internal medicine resident or gastroenterology fellow in this study so that patients can be enrolled. We intend to continue this study and will report as soon as patients are enrolled.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-49 Status: Ongoing

Title: Cell Culture to Test if MCF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone

Start date: Feb 94	Estimated completion date:
Principal Investigator: Gilberto Vigo, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Int Med Cl, Gen Med Svc	Associate Investigator(s): Kevin Carlin, M.D. Isidoro Chapa Albert Thomason, M.D.
Key Words: serum free medium, variable thyroid levels	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): MCF-7 an established breast cancer cell line will be grown in serum free medium with 2 million cells added to each of 4 flasks (as counted by coulter counter). Variable levels of thyroid hormone will be added to each of the 4 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate of the variable thyroid levels.

Technical Approach: MCF-7 breast cancer cells will be obtained from an established biological research firm. The cells will be at first grown in their optimum medium for several weeks until sufficient numbers are available. Then two million cells (as counted by coulter counter) will be added to each of four flasks. Serum free medium PFMR-4 from Sigma St Louis will be used as the culture medium. Details given in protocol.

Progress: Already reported to local ACP meeting, now being repeated to make sure the cells are independent of thyroid hormone.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-51 Status: Ongoing

Title: The Effect of Tetrac and Triac Upon Murine Bladder Cancer Cells in Cell Culture

Start date: Feb 94	Estimated completion date:
Principal Investigator: Andrew Chung, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Internal Med Cl, Gen Med/Medicine	Associate Investigator(s): Kevin Carlin, M.D. Isidoro Chapa Albert Thomason, M.D.
Key Words: Tetrac/Triac, Murine bladder cancer cells, serum free medium thyroid hormone analogs, Musculus	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): Murine bladder cancer cells will be grown in serum free medium with 2 million cells added to each of 5 flasks (as counted by coulter counter). Variable levels of Tetrac and Triac (thyroid hormone analogs) will be added to each of the 5 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate with the variable Triac and Tetrac levels.

Technical Approach: Murine transitional cell carcinoma (MBT 2) cells were obtained from an in vivo bladder tumor in 1990 and have been maintained in frozen state and cell culture since. Cells have episodically undergone passage thru mice (species Musculus, strain C3H). Two million (as counted by coulter counter) of these cells will be added to each of 5 flasks. Schedule outlined in protocol.

Progress: Project has been presented to local ACP meeting, now being repeated to make sure Triac/Tetrac inhibits cancer growth.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-53 Status: Ongoing

Title: A Randomized Clinical Trial Evaluating Topical Vitamin E Oil in the Treatment of Chemotherapy Induced Mucositis

Start date: 14 Feb 94	Estimated completion date:
Principal Investigator: Svetislava Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Vernon T. Lew
Key Words: Vitamin E Oil, Mucositis, high-dose chemotherapy, neoplasms	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
Total number of subjects enrolled to date: 9  
Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine by a prospective, randomized controlled trial, the efficacy of Vitamin E in the treatment of mucositis associated with high dose chemotherapy.

Technical Approach: High dose chemotherapy with autologous stem cell support has become an increasingly popular approach for the treatment of various neoplasms. It is used commonly in many hematologic malignancies such as AML, ALL and NHL as well as in an investigational role in some solid tumors like breast cancer. The morbidity and mortality associated with this therapy however is considerable and has limited its routine use. Details including drug information, patient eligibility, treatment plan and specifics are outlined in protocol.

Progress: Collecting data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-57 Status: Ongoing

Title: Blood Velocity, Valve Leaflet Flutter and Murmurs in Normal Teenagers

Start date: 14 Feb 94	Estimated completion date: Spring '98
Principal Investigator: J. Mark Moody, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Andrew T. Moody Sheri Y. Nottestad, M.D. Bernard J. Rubal, Ph.D.
Key Words: valve leaflet flutter, blood flow velocity	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 7  
Periodic review date: Feb of ea yr Review results: See below

Objective(s): To examine the hypothesis that normal subjects with murmurs are more likely to have valve leaflet flutter than those without murmurs and that these subjects also have higher blood flow velocity than those without murmurs.

Technical Approach: Subject population, clinical examination, echocardiographic equipment, data analysis/statistics, etc., outlined in protocol.

Progress: We have acquired data on seven patients so far; analysis incomplete, no problems encountered except slow recruiting.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: C-94-59                      Status: Ongoing

Title: A Phase I Trial of Navelbine in Combination with Estramustine in Patients with Hormone Refractory Prostate Cancer

Start date: 15 Nov 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words: Navelbine, Estramustine, Hormone Refractory Prostate CA	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Mar of ea yr Review results: Ongoing

Objective(s): To determine the maximally tolerated dose of Navelbine (vinorelbine tartrate) given as short intravenous injection on days 1 and 8 in combination with a fixed dose of estramustine given orally in three divided daily doses on days 1-21 with the regimen repeated every 28 days. To determine the quantitative and qualitative toxicities of the concomitant administration of Navelbine and estramustine. To determine the recommended dose for Navelbine and estramustine on this schedule.

Technical Approach: Patient Eligibility, study plan and specifics are outlined in protocol.

Progress: This study has recently been opened. No patients have been enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-60 Status: Completed

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Colon Cancer

Start date: 20 Dec 93	Estimated completion date: ?
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words: Ilmofofosine, Colon Cancer, sulfoxide, metabolite	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To assess the anti-tumor effect of a five-day (120-hr) continuous infusion if ilmofofosine administered at a dose of 300 mg/m<sup>2</sup>/day to patients with colon cancer. To assess the toxicity of ilmofofosine. To evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Patients 18 years of age and older with cytologically or histologically confirmed colon cancer. Further specifics in protocol.  
Exclusion criteria: Concurrent life threatening illness, inadequate renal, hepatic, or bone marrow function; performance status of 3 or 4; pregnancy.

Progress: Patient enrollment continues with an interim analysis at 20 patients.  
Jan 95: Accrual goals have been met. The results are being analyzed and a manuscript forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-64 Status: Ongoing

Title: Double Blind, Parallel Group Exploratory Study Comparing the Efficacy and Safety of Topitriol (Topical Calcitriol) with that of Vehicle in the Protection from Chemotherapy Induced Hair Loss, in Patients with Breast Cancer

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Topitriol, hair loss, doxorubicine, Cyclophosphamide, 5- fluorouracil	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
Total number of subjects enrolled to date: 11  
Periodic review date: Sep of ea yr Review results: Continue

Objective(s): To determine if 7 days of pre-treatment of the scalp with 0.0025% Topitriol leads to clinically significant (>50% reduction in hair loss) improvement in the alopecia associated with the use of a standard doxorubicin-containing regimen for the therapy of advanced breast cancer (CAF: Cyclophosphamide, Doxorubicin, and 5-Fluorouracil). The secondary objective is to determine if sufficient systemic absorption of Topitriol occurs with this application regimen to alter calcium metabolism in patients with advanced breast cancer.

Technical Approach: Experimental Design and Methods; Schedule of Assessments/Treatments; Patient Selection Criteria and other specifics are outlined in protocol.

Progress: Accrual to this study has recently been reinitiated. Patients will be receiving increased doses of Topitriol. Additional women with node positive breast cancer receiving adjuvant chemotherapy will be entered. Aug 95 Accrual will be completed with the next patient to be entered. Results have been disappointing to date, with minimal impact on alopecia observed. A different preparation will be considered before additional trials are conducted.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-66 Status: Ongoing

Title: An Open Label, Multicenter, Phase I/II, Dose Escalating Tolerance and Safety Study of Glycosylated Recombinant Human Interleukin-6 (r-hIL-6) in Patients Receiving Chemotherapy"

Start date: 1 Dec 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTRC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Interleukin-6 (r-hIL-6), myelosuppressive, hematopoietic, attenuated thrombocytopenia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 2  
Periodic review date: Sep of ea yr Review results: Continue

Objective(s): To assess the safety and tolerance of administering repetitive daily subcutaneous doses of r-hIL-6 to patients with solid tumors before and after myelosuppressive chemotherapy. To identify for future clinical testing a safe and recommended dose and/or maximum tolerated dose of r-hIL-6 by means of cohort dose escalations. To perform study-associated laboratory based investigations which will provide insight into the biologic actions of r-hIL-6 in vivo. To perform study-associated laboratory based investigations which will provide insight into the biologic actions of r-hIL-6 in vivo. To evaluate the rate of hematopoietic recovery after myelosuppressive chemotherapy, and to determine any preliminary evidence of efficacy from r-hIL-6 which may be apparent in terms of attenuated thrombocytopenia or accelerated platelet count recovery.

## Technical Approach:

Progress: Dose escalation proceeds on this study. Good thrombopoietic effect has been observed with IL6, and good antitumor activity with the carboplatin. Toxicities have included flu-like symptoms and low grade fevers. Preliminary results were presented at the American Society of Hematology (ASH) meeting in Dec 93.

Aug 95: Significant toxicities manifested by flu-like symptoms and fever/chills were observed at the 20 mg/kg level. Thrombopoietia was alleviated with IL-6, but the toxicities have been substantial and more patients will be tested with the 3rd 10 mg/kg dose level.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-68 Status: Ongoing

Title: A Phase I/II Study of SDZ PSC 833 with Doxorubicin, Vincristine, Cyclophosphamide and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: David A. Rinaldi, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D.
Key Words: Doxorubicin, Vincristine, Cyclophosphamide, Prednisone, Non- Hodgkin's, refractory, relapsed	Howard A. Burris, III, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Sep of ea yr Review results:

Objective(s): To study the safety and tolerability of SDZ PSC 833 in combination with doxorubicin, vincristine, cyclophosphamide and prednisone (P-DVCP). To evaluate the efficacy (i.e., complete response rate and duration disease free and overall survival) of P-DVCP in refractory or relapsed intermediate or high grade non-Hodgkin's lymphoma (NHL). To determine the MTD of P-DVCP. To study the correlation of *mdrl* gene expression in tumor specimens with clinical response to P-DVCP.

Technical Approach: Study population, treatment assignment, medication, visit schedule/evaluation and other specifics are outlined in protocol.

Progress: No patients have been eligible at BAMC. Six patients at other sites have been treated, with significant neutropenia and fever seen in four. The protocol is to be amended to allow a reduction in the dose of doxorubicin. Aug 95: Accrual is slow in this very specific patient population of refractory lymphomas. Excellent responses have been observed, with several complete remissions documented. The liver dosage regimen has been very well tolerated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-69 Status: Ongoing

Title: Phase II Trial of Taxotere in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Taxotere, HRPC, PSA, Karnofsky performance status, pain palliation	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Sep of ea yr Review results: Continue

Objective(s): To assess the antitumor effect of taxotere in patients with hormone refractory prostate cancer (HRPC) as measured by decline in serum prostate specific antigen (PSA). To assess the clinical benefit of intravenous taxotere in patients with HRPC as measured by time to disease progression, Karnofsky performance status, and pain palliation. To determine the objective response rate of intravenous taxotere in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous taxotere in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration, and detailed specific are outlined in protocol.

Progress: Accrual goes slowly. No unexpected toxicities to date. Some hints of clinical benefit observed.

Aug 95: Accrual continues to be slow with 7 patients entered in San Antonio. Clinical benefit has been seen in several patient; well-tolerated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-72 Status: Ongoing

Title: Comparison of Cost Effectiveness of Visual Blood Glucose Monitoring and One Touch in An Outpatient Diabetic Clinic: Effects on Glycosylated Hemoglobin

Start date: 25 Mar 94	Estimated completion date:
Principal Investigator: Rosemary Chacko, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gen Med Svc	Associate Investigator(s): Richard Marple Linore Bouska
Key Words: Glycosylated Hemoglobin, Glucose V	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Compare patient interpretation of the Glucose V visual blood glucose test with the One Touch mechanized display. 2. To follow patients placed on the Glucose V visual blood glucose test to see if the diabetic control based on glycosylated hemoglobin has worsened. 3. To delineate subgroups of patients that may utilize Glucose V visual blood glucose tests at significant cost savings compared to the One Touch, without harm to overall diabetic control.

Technical Approach: Most patients will show significant worsening of glycosylated hemoglobin with Glucose V when compared with One Touch.

Progress: Due to the recent delivery and maternal leave of MAJ Chacko and the pending delivery and maternal leave of CPT Bouska, this project has not been started. We anticipate starting this fall 94.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-79 Status: Terminated

Title: Influence of Hyperimmune Serum Products on Panel Reactive Antibody Determinations

Start date: 7 Apr 94	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): William W. ward, BSC Ted Freeman, M.D. Elizabeth M. Menchaca, DAF Linda K. Porter, DAC
Key Words: Hyperimmune, Klebsiella, Pseudomonas, nosocomial	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12  
Total number of subjects enrolled to date: 12  
Periodic review date: Review results:

Objective(s): To study the effect of administration of a hyperimmune serum against Klebsiella and Pseudomonas on the panel reactive antibody assay.

Technical Approach: Ten pre- and post-infusion serum specimens from the Federal Hyperimmune Immunotherapy Trial (FHIT) will be chosen for PRA determinations. The FHIT is an ongoing randomized placebo-controlled trial to determine the effectiveness of a hyperimmune serum obtained from volunteers who had been immunized with a combined Klebsiella/Pseudomonas capsular vaccine in preventing nosocomial infections.

Progress: Serum has been collected and awaiting to be processed.  
4/95: PI left and study terminated:

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: C-94-82                      Status: Ongoing

Title: A Randomized, Double-Blind Study Comparing Megace Plus Hydroxyurea to Megace Plus Placebo in Patients with Advanced Cancer

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Megace, Hydroxyurea, placebo	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Jan of ea yr Review results: Continue

Objective(s): The primary endpoint for this study is to determine whether low dose of hydroxyurea prolongs survival in patients with advanced cancer. To determine the toxicity of low dose hydroxyurea plus megace in patients with advanced cancer. To determine the impact of hydroxyurea on quality of life of patients with advanced cancer.

Technical Approach: Background/rationale, drug information, patient eligibility, treatment plan and other specifics are outlined in protocol.

Progress: Accrual goes well to this study. The double-blinded nature of the protocol prevents any preliminary analysis. No unexpected toxicities to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-84 Status: Completed

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Non-Small Cell Lung Cancer

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Ilmofofosine, Non-Small Cell Lung Cancer, intravenous, toxicity, Sulfoxide	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results: Continue

Objective(s): To assess the antitumor effect of five day (120-hr) infusion of intravenous ilmofofosine in patients with non small cell lung cancer; to assess the toxicity of ilmofofosine; and to evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Detailed study plan, methods and other details are outlined in protocol.

Progress: Accrual continues to a total of 20 patients. No antitumor activity has been observed to date. Sporadic, ill-defined pulmonary toxicity has been observed in several patients.

Mar 95: Accrual goals have been met. Results are being analyzed and manuscript forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-85 Status: Ongoing

Title: A Phase I Study of Docetaxel (RP56976) and 5-Fluorouracil Combination Chemotherapy in Patients with Advanced Solid Tumor

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Docetaxel, 5-Fluorouracil, advanced solid tumors, first-line chemotherapy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Jan of ea yr Review results: Continue

Objective(s): Phase I: To determine the maximum tolerated doses (MTD) of docetaxel and 5-FU in combination, when given to patients with advanced solid tumors. Phase II: To determine the efficacy of docetaxel and 5-FU in combination as first line chemotherapy in advanced breast cancer, with evaluation of objective response rate, duration of response, and time to disease progression.

Technical Approach: Entry criteria, plan of the study, data analysis and other specifics outlined in protocol.

Progress: Sporadic toxicities, not felt to be drug related, have necessitated adding additional dose levels and patients to this trial. Accrual goes well and good antitumor activity has been observed with this combination.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-86 Status: Ongoing

Title: Serum Collection Study on Patients with Active Colon or Breast Cancer

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: monoclonal antibodies, nuclear matrix proteins (NMP), sera, immunoassays	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Sep of ea yr Review results:

Objective(s): To evaluate monoclonal antibodies for cancer specific nuclear matrix proteins (NMP) utilizing well documented sera from patients with breast or colon cancer. Identify immunoassays capable of detecting breast or colon cancer in human serum.

Technical Approach: Eligibility criteria, study design, and detailed specifics are outlined in protocol.

Progress: This trial has not been initiated as the statistical parameters to be utilized have not been properly defined.  
Aug 95: It is anticipated that the sponsor will not pursue this trial design at present.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-88 Status: Ongoing

Title: A Double-Blinded, Randomized Trial Comparing Zidovudine (ACV) vs, ZDV + Didanosine (ddI) vs, ZDV + ddI + Nevirapine in Asymptomatic Patients on ADV Monotherapy Who Develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA

Start date: 14 Apr 94	Estimated completion date:
Principal Investigator: M. Patricia Joyce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words: Zidovudine (ACV), Didanosine, mutation, transcriptase, serum/plasma, viral RNA, codon 215	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: May of ea yr Review results:

Objective(s): Primary: 1. To validate that alteration of codon 215 of reverse transcriptase in plasma virus precedes the increase in viral burden as measured in the peripheral blood and decline in CD4 count which have been observed in association with clinical failure on zidovudine. 2. To determine whether alternative regimens of antiretroviral agents alter the course of viral burden as measured in the peripheral blood and CD4 changes when initiated on the basis of plasma RNA PCR results.

Technical Approach: Patient selection/enrollment, study treatment, clinical/laboratory evaluations and other specifics are outlined in protocol.

Progress: This double blinded study is to continue next 4-5 years. The two patients are tolerating fine, no side effects.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-89 Status: Ongoing

Title: A Randomized, Controlled, Multicenter Trial of Filgrastim (Recombinant-methionyl Human Granulocyte Colony Stimulating Factor) for the Prevention of Grade 4 Neutropenia in Patients with HIV Infection

Start date: 5 Apr 94	Estimated completion date:
Principal Investigator: C. Kenneth McAllister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease Svc	Associate Investigator(s):
Key Words: Filgrastim, Human Granulocyte Colony Stimulating Factor, Grade 4 Neutropenia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of Filgrastim (r-metHuG-CSF) for the prevention of Grade 4 neutropenia (ANC<500/mm<sup>3</sup>) in patients with HIV infection.

Secondary: To compare the incidence of culture confirmed bacterial infections and fungal infections, use of IV antibacterial and antifungal agents, use of myelosuppressive drugs, and hospitalizations in patients randomized to Filgrastim treatment versus patients randomized to observation. To compare all adverse events and the incidence of death in patients randomized to Filgrastim treatment versus patients randomized to observation.

Technical Approach: Background and rationale, experimental plan, patient eligibility/enrollment, study drugs, treatment procedures and further details are outlined in protocol.

Progress: Patient is about to complete a 6-month study period without complication. Drug company wants him to go on open label drug but still working on the funding of this.

4/95: There is a single patient entered into this study. The protocol is no longer enrolling. The patient is expectant and PI's understanding is the protocol remains open as long as patient is alive.

11/95: This double blinded study is to continue next 4-5 years. The two patients are tolerating fine, no side effects.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-90 Status: Ongoing

Title: Cognitions, Depression, Quality of Life, and Will-to-Live in Lung Cancer Patients

Start date: 11 Apr 94	Estimated completion date:
Principal Investigator: Brenda J. Moretta, Doctoral Candidate	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology Svc	Associate Investigator(s): Jean M. Johnson, Ph.D. RN Timothy O'Rourke, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 29 BAMC; 68 total  
 Total number of subjects enrolled to date: 29  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): Attempt to study the relationships between cognitive appraisals, depression, quality of life, and will-to-live in lung cancer patients.

Technical Approach: Characteristics of subjects, subject recruitment, measures, confidentiality of data, etc, covered in protocol.

Progress: Data collection has been completed. Data analysis is nearly complete and my dissertation should be completed in January.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-95 Status: Ongoing

Title: The Effect of Acemannan on UVB-Induced Erythema

Start date: 9 May 1994	Estimated completion date:
Principal Investigator: Vincent L. Angeloni, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology Service	Associate Investigator(s): Dirk Elston, M.D. Richard Vinson, M.D.
Key Words: Acemannan UVB-Induced Erythema, banal hydrogel, double-blinded	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2\*  
 Total number of subjects enrolled to date: 2  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate whether topical application of acemannan has any beneficial effect on the erythema induced by ultraviolet B light (i.e. sunburn) when applied before and after light exposure. The study will utilize healthy volunteers who will be exposed to a measured dose of ultraviolet B (UVB) to small areas of non-sun exposed skin which have been treated with acemannan gel before exposure and after exposure. The resulting erythema will then be evaluated to discern any effect induced by the application of the acemannan.

Technical Approach: The hypothesis to be tested in this experiment is that acemannan applied to the skin will either attenuate the erythema induced by UVB exposure or enhance its resolution. Thus, we will evaluate the UVB responses of untreated skin, skin treated with a banal hydrogel (K-Y jelly) and skin treated with acemannan gel. Erythema responses will be quantified visually in a double-blinded fashion.

Progress: 5/95: \*Two patients have been enrolled and have completed the study. No adverse effects have been encountered. We currently have 5 additional patients who will be enrolled and processed through the study when we accumulate more volunteers. It is anticipated that completion of the study will be within the next 3-4 months.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-99 Status: Ongoing

Title: A Phase I Study to Determine the Maximum Tolerated Dose of Topotecan Following Oral Administration Over 10 or 21 Days in Patients with Malignant Solid Tumors

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Frank W. Cobb, M.D. Gail Eckhardt, M.D. Ralph F. Heaven, M.D. Stephen Kalter, M.D. Timothy J. O'Rourke, M.D.
Key Words: Topotecan, dose levels, antitumor activity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Feb of ea yr Review results:

Objective(s): To determine the qualitative and quantitative toxicity of Topotecan when given by oral administration over 21 out of every 28 days and to establish an MTD using this schedule. To determine pharmacokinetics and steady state levels achieved after prolonged oral dosing over a range of dose levels and to document any antitumor activity observed using this schedule.

Technical Approach: Study population, conduct of the study, study medication, etc, outlined in protocol.

Progress: Accrual has recently been initiated to this study. No unexpected toxicities observed to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-103 Status: Completed

Title: Safety and Immunogenicity of a Cell Cultured Vaccinia Virus Vaccine (TSI-GSD-241) Administered by the Intradermal and Intramuscular Routes Compared with Wyeth Dryvax Administered by Scarification

Start date: 16 June 1994	Estimated completion date:
Principal Investigator: Shannon Harrison, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Curtis Yeager, MAJ, MS Michael S. Wright, CPT, MS
Key Words: Dryvax, Scarification, intradermally, intramuscularly	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: June of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the safety and immunogenic potency of a cell cultured vaccinia virus vaccine candidate administered intradermally and intramuscularly with the Wyeth Dryvax vaccine administered by scarification. This open label study seeks to enroll up to 114 volunteers, who will be divided into 3 groups based upon randomization. Volunteers will receive the vaccines at the clinical unit of BAMC or at a designated treatment area at the Academy of Health Sciences.

Technical Approach: Selection of volunteers, study population, screening, criteria for acceptance, etc, covered in protocol.

Progress: Approximately 100 subjects were recruited from 3 different AHS classes. Subjects received 1) Wyeth Dryvax by scarification, or new cell-cultured vaccinia vaccine by 2) intradermal or 3) intramuscular. Subjects were monitored and tested for overall health and virus titer for 28 days. Results are pending data analysis.  
 Publication is being generated for submission. (Apr95)

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-105 Status: Ongoing

Title: The Use of Albuterol in the Premedication of Patients with Chronic Obstructive Pulmonary Disease Undergoing Routine Flexible Fiberoptic Bronchoscopy

Start date: 21 Jun 94	Estimated completion date:
Principal Investigator: John Atkins, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): Mark D. Peacock, M.D. Herman M. Blanton, M.D.
Key Words: Albuterol, flexible fiber-optic bronchoscopy (FFB), nebulized	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 10  
Periodic review date: Jun of ea yr Review results:

Objective(s): To evaluate the effect of premedication with nebulized albuterol upon post-procedural complication rates in patients with chronic obstructive pulmonary disease (COPD) undergoing routine flexible fiberoptic bronchoscopy (FFB).

Technical Approach: Adult male and female patients with a clinical history consistent with COPD and with spirometric evidence of an obstructive ventilatory defect, that are to undergo a medically indicated bronchoscopic procedure. The criterion for a significant obstructive ventilatory defect is a difference of at least 9% between the predicted FEV<sub>1</sub>/FVC ratio and the actual FEV<sub>1</sub>/FVC ratio in women and a similar difference of 8% in men. All subjects will not use any inhaled bronchodilators four hours prior to the procedure.

Progress: Seven patients have been enrolled to date; no complications have been noted in either group.

Jun95: Ten patients have been enrolled to date, goal of 50 is anticipated.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-106 Status: Completed

Title: A Phase II Trial of Iriotecan Hydrochloride (CPT-11) for Patients with 5-FU-Refractory Colorectal Cancer

Start date: 11 Jun 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O. Rourke, M.kD. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Irinotecan Hydrochloride, 5-FU, active metabolite	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): To assess the antitumor activity of irinotecan (CPT-11) when administered once a week for 4 consecutive weeks, followed by a 2 week rest, in patients with metastatic colorectal cancer that has progressed within 6 months of one prior 5-fluorouracil (5-FU)-based chemotherapy. To evaluate the qualitative and quantitative toxicities of irinotecan on the schedule in this population. To ascertain the pharmacokinetics of irinotecan and the active metabolite (SN-38) in this population.

Technical approach: Staging criteria, eligibility, exclusion, treatment plan, dosage modifications, etc., details covered in protocol.

Progress: Rapid accrual has been accomplished. 19 patients were entered in San Antonio with a total of 200 enrolled nationally. Results are not yet available regarding antitumor efficacy.

May 95: A manuscript for this trial is being completed. An overall response rate (unconfirmed) of 17% was noted. Plans are being made to submit CPT-11 for FDA approval in this disease study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-109 Status: Ongoing

Title: Gastric Hyposecretion in Patients with Walter Reed Stage 6 HIV-1 Infection

Start date: 23 Jun 94	Estimated completion date: 12 Feb 94
Principal Investigator: Charles A. Farrington, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology Service	Associate Investigator(s): Shailesh C. Kadakia, M.D. Patricia Joyce, M.D. Richard Schaeffer, M.D.
Key Words: cutaneous anergy, gastric acid secretion, WR-6	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 6  
Periodic review date: Jun of ea yr Review results:

Objective(s): To investigate a population of WR6 AIDS patients prospectively for incidence of AIDS associated gastric secretory failure, and survey them for incidence of chronic diarrhea so as to determine if the secretory failure is associated with an increased frequency of chronic diarrhea.

Technical Approach: Twenty-six subjects with WR Stage 6 AIDS will be required. Ten healthy age-matched control volunteers will serve for comparison of gastric acid secretion between the two groups. Selection of patients for the study will be based on the Walter Reed Staging System for HIV-1 infection. All patients will have clinical AIDS, defined as WR-6. This is defined as being positive for HIV, having a T4 cell count < 400, partial or complete cutaneous anergy, and the presence of opportunistic infections other than thrush. Further details outlined in protocol.

Progress: Two HIV-6 patients enrolled to date. Neither patient had a complaint of chronic diarrhea and neither patient was found to have gastric acid hyposecretion.

Jun95: Four additional WR-6 HIV patients enrolled since last reporting date for a total of 6 enrolled patients to date. All 6 patients had normal gastric acid secretion. No significant difference in gastric acid secretion has been seen in the HIV patients and the controls. One patient of the six has chronic diarrhea. It is anticipated that one or two more patients will be enrolled in the next few weeks and that the study will be completed by mid-June.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-110 Status: Ongoing

Title: A Prospective Randomized Double-Blind Study Comparison of Flexible Fiberoptic Bronchoscopy with and without the Use of Preprocedure Sedation

Start date: 28 Jun 94	Estimated completion date:
Principal Investigator: James P. Bradley, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease Service	Associate Investigator(s): Mark D. Peacock, M.D.
Key Words: Flexible Fiberoptic Bronchoscopy, respiratory depression, cardiac arrhythmias	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
Total number of subjects enrolled to date: 30  
Periodic review date: Jun of ea yr Review results:

Objective(s): Over 50% of life threatening complications from flexible fiberoptic bronchoscopy are from the premedications given, and are primarily due to respiratory depression and cardiac arrhythmias. The majority of procedures are performed on an outpatient basis; therefore, cost containment from medications given, observation required, as well as the need for hospitalization are important. A prospective study is needed to compare outcomes with and without use of premedication during flexible fiberoptic bronchoscopy for tolerance and whether a significant time and cost savings can be realized.

Technical Approach: Subjects - Male and female patients older than 18 years of age, who require routine bronchoscopy, will be asked to volunteer to participate in this study. After informed consent is obtained, patients will be randomized to two groups. The study group will be premedicated with atropine, 0.6mg, and versed, 0.07 mk/kg, intramuscularly. The control group will be given a placebo consisting of normal saline IM in equal volumes given the first group. Both groups will get the injection 30 minutes prior to the start of the procedure. The patient, the technician, and the bronchoscopist will be blinded to the premedication given.

Progress: Enrollment to begin September 1994.  
Jun95: Anticipate enrolling 100 patients. No side effects have been experienced. So far it appears that patients do prefer sedation with bronchoscopy.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-112 Status: Ongoing

Title: Phase II Study: Treatment of Lymphoma with High-Dose Chemotherapy Consisting of BCNU, Cytosan, and VP-16 with Autologous Stem Cell Support and Cyclosporine-A Immunomodulation

Start date: 6 Jul 94	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13  
 Total number of subjects enrolled to date: 23  
 Periodic review date: Jul ea yr Review results:

Objective(s): To assess the efficacy of high dose BCNU, VP-17, and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis Hodgkin's disease or high- or intermediate-grade non-Hodgkin's lymphoma.

Technical Approach: Eligibility criteria, treatment plan, drug information and detailed specifics are given in protocol.

Progress: We will also add cyclosporin to the regimen to improve results.  
 Jun 95: Since Sep 94 we have added cyclosporin (CSA) to CBV regimen; 7 patients were done on CBV with CSA. There was one BMT related death; one patient relapsed and died due to dosage, the other patients are well to date. From the original protocol Jan 93; 15 patients were done since then on CBV without CSA there are 9/15 alive (last F/U Jun 95 = 60%; of which 46% or 7 patients of 15 are dosage free in complete remission; 2/15 = 1% relapsed but alive; 6 patients that died one died secondary to VOD and CNS bleed, one 2° to fungal infection and the other 4 died due to progressive disease, not a transplant related mortality. Longest F/U is 30 mo; shortest F/U 30 days.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-123 Status: Terminate

Title: Evaluation of Cardiac Output Determination by the MedGraphics Gas Analysis System Using Invasive Thermodilution and Standard Metabolic Cart Comparisons

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Ricky D. Latham, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Bernard J. Rubal, Ph.D. William T. Wright, M.D. Suzanne M. Fortney, Ph.D.
Key Words: Invasive thermodilution, MedGraphics Gas Analysis, MedGraphics metabolic cart	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Compare cardiac output determinations during exercise using a noninvasive CO2 rebreathing device to the standard thermodilution catheter.  
2. Compare oxygen consumption determinations using the MedGraphics Gas Analysis system vs the standard MedGraphics metabolic cart.

Technical Approach: Subjects eligible will be those scheduled to undergo routine elective right and left heart catheterization. Inclusion/exclusion specifics, data analysis, risks and other details outlined in protocol.

Progress: Jul 95: No additional patients were added because of NASA software development problems.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-126 Status: Ongoing

Title: A Pilot Study of Docetaxel (RP 56976) in Patients with Paclitaxel-Resistant Advanced Breast Cancer

Start date:	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: CTRC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the objective response rate, duration of response, and toxicity of docetaxel in patients with Stage IV paclitaxel-resistant breast cancer. To examine changes in quality of life over time in patients receiving docetaxel and to correlate scores with response and with toxicity frequencies.

Technical approach: Study objectives, patient identification, plan of the study and further details are covered in protocol.

Progress: A total of 6 patients have been enrolled on this study, with 2 patients exhibiting a reduction in their tumor size. No new toxicities noted. Accrual continuing as planned.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-127 Status: Completed

Title: A Phase I Study of SCH 52365 in Adult Patients with Advanced Cancer Stratified by Extent of Prior Therapy

Start date: 18 Apr 94	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 5  
Periodic review date: Review results: Completed

Objective(s): To characterize the safety profile and determine the DLT and MTD of SCH 52365 when administered orally, once a day for 5 days in adult patients with advanced cancer who have no bone marrow involvement with tumor and who have been heavily pretreated with therapy defined as poor risk. To characterize the safety profile and determine the DLT and MTD of SCH 52365 when administered orally, once a day for 5 days in adult patients with advanced cancer who have no bone marrow involvement with tumor and who have been less heavily pretreated with therapy defined as good risk. To characterize the single- and multiple-dose pharmacokinetics of SCH 52365 in both these patient populations.

Technical Approach: Study design, patient population, conduct of study, treatment and further details outlined in protocol.

Progress: Accrual is nearing completion. Dose limiting toxicities include thrombocytopenia and neutropenia. Responses have been noted in patients with sarcoma and melanoma.

Aug 95: Closed as accrual goals have been met. Results are being analyzed and manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-129 Status: Completed

Title: Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and Helicobacter pylori Infection

Start date: 9 Aug 94	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastro Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 3 at BAMC  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The primary objectives of this study are to assess the clinical outcomes and medical costs of treatment with clarithromycin plus omeprazole versus omeprazole alone or ranitidine alone in the treatment of patients with a duodenal ulcer who have a confirmed H. pylori infection. The clinical response of the patient will be used as the primary measurement of efficacy. All utilization of medical care related to duodenal ulcer, both direct and indirect, will be collected for the entire study period.

Technical Approach: Study design/description, patient selection criteria, exclusion criteria, study materials, and further details are outlined in protocol.

Progress: Aug 95: Data is being analyzed and report as to results will be forthcoming.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-130 Status: Ongoing  
 Title: Spanish Translation and Validation of a Quality of Life Questionnaire

Start date: 11 Aug 94	Estimated completion date: 29 Sep 95
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc Svc	Associate Investigator(s): Ian M. Thompson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 122  
 Total number of subjects enrolled to date: 122  
 Periodic review date: Aug ea yr Review results: \_\_\_\_\_

Objective(s): Cancer and its treatment can affect any one of the following areas of life: physical functioning; emotional functioning; general symptoms; symptoms commonly associated with treatment for breast and prostate cancer; general health and quality of life. It is very important to have a patient's view of how he or she has been feeling during the treatment. This information can help the physician and patient make decisions about the best care for the patient.

Technical Approach: Study procedures and further details outlined in protocol.

Progress: Aug 95: No progress reported/no adverse events.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-131 Status: Completed

Title: Attitudes of Physicians Regarding Blood Transfusion Therapy and Blood Donation

Start date:	Estimated completion date:
Principal Investigator: Leonard E. Deal, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): Mark D. Peacock, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To identify physician attitudes towards the replenishment of blood supplies and to evaluate them within the context of the physicians' utilization of these stores.

Technical: A questionnaire will be used in an attempt to survey every physician assigned to BAMC. Initial effort will be contacting every departmental chief and ask permission to discuss the purpose of this survey with their physicians during a routine, scheduled meeting for that department. The results of the surveys will be analyzed with respect to level of training, medical specialty, and transfusion ordering habits. Statistical comparisons of transfusion rates will be compared by the Chi-square test of independence (for donat vs. do not donate) and the rank sum test.

Progress: Jul 95: Project completed: 317 physicians of BAMC were surveyed to ascertain the number of physicians who regularly donate blood as well as to find out the percentage of physicians who perceive a problem with access to blood products. The two groups were then compared to determine if perceptions of access problems influenced an individual's decision to donate blood. the overall rate of donation among physicians at BAMC was 25% (compared to national average of 5%) and rates of donations among physicians in individual departments were not influenced by perception of access problems.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-135 Status: Completed

Title: A Phase II Multicenter Clinical Trial to Evaluate the Safety, Efficacy and Pharmacokinetics of MP 840 Given Every Four Weeks (Q4W) in Patients with Advanced Refractory Colorectal Cancer

Start date: 20 Jun 94	Estimated completion date:
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Oncology Staff and Fellows
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the objective response rate in patient with advanced refractory colorectal cancer treated with DMP 840 once every 4 weeks. To characterize the safety profile of DMP 840 in this patient population. To evaluate secondary effectiveness parameters such as duration of objective response, time to disease progression, survival, and changes in performance status and weight.

Technical Approach: The enrollment period for this study is expected to be 12 months. Each patient will be treated with a six-hour central venous infusion of DMP 840 on a once every 4 weeks schedule. The starting dose will be 60 mg/m<sup>2</sup> of DMP 840 for good risk patients and 50 mg/m<sup>2</sup> for poor risk patients. Blood samples of DMP 840 pharmacokinetic analysis will be obtained during the first course of treatment. Objective response will be evaluated by the measurement of indicator lesions once every two courses. Further details outlined in protocol.

Progress: Accrual has proceeded rapidly with this trial. The initial 20 patients have been accrued and we are awaiting documentation of objective responses before proceeding to the second phase of accrual.  
May/95: Study is closed as accrual goals have been met. The results are being analyzed and a manuscript will be forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-136 Status: Completed

Title: A Phase II Multicenter Clinical Trial to Evaluate the Safety, Efficacy and Pharmacokinetics of DMP 840 Given Every Four Weeks (Q4W) in Patients with Advanced Refractory Breast Cancer

Start date: 20 Jun 94	Estimated completion date:
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jun of ea yr Review results: Completed

Objective(s): To determine the objective response rate in patients with advanced refractory breast cancer treated with DMP 840 once every 4 weeks. To characterize the safety profile of DMP 840 in this patient population. To evaluate secondary effectiveness parameters such as duration of objective response, time to disease progression, survival and changes in performance status and weight.

Technical Approach: This is an open-label, non-randomized, multiple dose, multicenter Phase II trial.

Progress: This trial has recently been initiated and no patients have been accrued to date. A total of 20 patients will be enrolled from four centers at which time patients will be evaluated to determine whether objective responses have been obtained.

May/95: Accrual goals have been met. The results are being analyzed and manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-137 Status: Completed

Title: The Coronary Stent in the Treatment of Cases Which Have Failed Standard Nonsurgical Techniques and Cases Predisposed to a Poor Outcome

Start date: 24 Aug 94	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of the PALMAZ-SCHATZ™ coronary stent in the treatment of cases that have failed standard nonsurgical techniques such as suboptimal PTCA or threatened abrupt closure or are cases where standard nonsurgical or surgical techniques are at high risk to have an outcome complicated by death or myocardial infarction. Initial success will be defined as successful deployment of the stent, achieving patency of the target artery with a residual stenosis < 50% and no major complication (death, MI, bypass of the target lesion).

Technical approach: Details outlined in protocol.

Progress: Jul 95: Stent has now been FDA approved so its use in this setting is no longer on protocol. Protocol closed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-143 Status: Ongoing

Title: Thrombus Formation During Coronary Angioplasty in Acute Ischemic Syndromes: Influence of Contrast Media

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas Ebersole, M.D. William Wright, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: ?  
Total number of subjects enrolled to date: ?  
Periodic review date: Sep of ea yr Review results: Continue

Objective(s): To determine if contrast media (ionic vs nonionic) impacts on the incidence of thrombus formation during coronary angioplasty in patients with unstable angina pectoris.

Technical Approach: The choice of contrast agent may affect the incidence of thrombus formation, acute ischemic complications and costs. This study will help define if ionic or nonionic contrast media should be utilized in patients with unstable ischemic syndromes undergoing coronary angioplasty. Further details outlined in protocol.

Progress: Sep 95: Still enrolling patients; nearing completion.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-146 Status: Ongoing

Title: A Phase III Trial of Crismatol Mesylate vs BCNU in the Consolidative Treatment of Glioblastoma Multiforme

Start date: 03 Mar 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Audie Murphy, CTRC, UTHSCSA, BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date: Review results:	

Objective(s): 1. Primary: To determine whether a year of consolidative chemotherapy with crisnatol mesylate is superior to a year of consolidative BCNU as measured by time to tumor recurrence in patients with glioblastoma multiforme. 2. Secondary: To determine whether a year of consolidative chemotherapy with crisnatol mesylate is superior to a year of consolidative BCNU as measured by overall survival in patients with glioblastoma multiforme. Additional endpoints: To gather information regarding the quality of life in patients receiving consolidative chemotherapy for glioblastoma multiforme and to obtain additional safety and toxicity information on crisnatol mesylate.

Technical Approach: Detailed information including preclinical studies, clinical trials, drug information, eligibility criteria, etc., included in protocol.

Progress: Accrual has been slow to this trial because of stringent eligibility criteria. Preliminary results from other centers prove that this design is feasible to complete and attempts at accrual will continue.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-151 Status: Completed

Title: Phase I Oral Bioavailability Study of Topotecan

Start date: 18 Apr 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 5  
Periodic review date: Review results: Completed

Objective(s): Characterize the bioavailability of topotecan following single oral administration compared to a single intravenous infusion. Determine the approximate bioequivalent oral to intravenous dose for topotecan. Assess the antitumor activity of topotecan.

Technical Approach: Pharmaceutical data, patient eligibility criteria, exclusion criteria, treatment plan and further specifics are outlined in protocol.

Progress: This trial is complete and will be presented at the American Society of Clinical Oncology this spring (May 95). The topotecan was well absorbed orally (bioavailability 48%) with no significant toxicities. Activity was pretest against ovarian and non-small cell lung cancer. Jul 95: Closed as accrual goals have been met. Results are being analyzed and a manuscript is forthcoming.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-153 Status: Completed

Title: An Open-Label, Multicenter, Non-Comparative, Study of Topotecan as Single Agent, Second-Line Therapy (Administered Intravenously as Five Daily Doses Every 21 Days) in Patients with Small Cell Lung Cancer

Start date: 25 Jul 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jul of ea yr Review results:

Objective(s): To evaluate the response rate, response duration, and survival in patients with advanced small cell lung cancer who are either refractory or potentially sensitive to first-line chemotherapy and are treated with single agent topotecan administered as five daily 30 minute infusions every 21 days. Secondary: To evaluate the time to response, time to progression, and symptoms of disease in patients with advanced SCLC treated with topotecan administered on this schedule. To evaluate the qualitative and quantitative toxicities of topotecan administered on this schedule.

Technical Approach: Study design overview, population, conduct of the study, screening evaluation and other specifics are outlined in protocol.

Progress: This study has recently opened to accrual. No patients have been enrolled to date and no preliminary results are available from other centers.

Nov 95: Study closed as accrual goals have been met. REsults are being analyzed and manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-154 Status: Completed

Title: Navelbine Treatment IND for Patients with Unresectable Stage II or IV Non-Small Cell Lung Cancer

Start date: 25 Jul 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To make intravenous NAVELBINE available to patients with unresectable Stage III or IV NSCLC who are not candidates for more aggressive local therapy while the FDA reviews the safety and efficacy of intravenous NAVELBINE for treatment of patients with advanced NSCLC. Patients with unresectable Stage III NSCLC are to be treated with NAVELBINE plus cisplatin. Stage IV patients may be treated with single-agent NAVELBINE or NAVELBINE plus cisplatin depending upon patient and physician choice. To gather additional information on the safety profile of weekly intravenous NAVELBINE therapy. To monitor response to treatment, time-to-disease progression and survival time of patients treated with intravenous NAVELBINE on a weekly schedule.

Technical Approach: Study design, general study procedures, drug administration, dose modifications, and other specifics are outlined in protocol.

Progress: This compassionate use protocol will remain open until Navelbine is officially approved by the FDA. Patients continue to benefit from the use of Navelbine in this disease.

Feb 95: Completion requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-155 Status: Completed

Title: Postural Changes in Atrial Filling Fraction with Congestive Heart Failure: An Echocardiographic Assessment

Start date: 26 Sep 94	Estimated completion date:
Principal Investigator: Michael Kwan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. To assess atrial function using Doppler echocardiography in decompensated congestive heart failure patients. 2. To compare changes in atrial function in the supine and 80° upright tilt positions as assessed by E and A wave magnitudes, E to A wave ratios, atrial filling fraction, atrial filling force, deceleration time, isovolumic relaxation time, and left atrial size. 3. To assess atrial function using Doppler echocardiography in these same patients after medical management and return to compensated CHF. 4. To compare postural changes in atrial function in age-matched subjects without a history of documented cardiovascular disease.

Technical Approach: Medical application and methods are outlined in protocol.

Progress: Aug 95: Completed May 95; paper being submitted.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-158 Status: Terminated

Title: Correlation of Liver Histopathologic Findings with Hepatic Clearance of Caffeine

Start date:	Estimated completion date: 3 yrs
Principal Investigator: Timothy P. Pfanner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Israel Crespo, M.D. Thomas Brewer, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: Terminated

Objective(s): To correlate hepatic function as measured by caffeine clearance with liver histopathologic changes in all patients in whom present for liver biopsy. To compare the correlation coefficient of caffeine clearance and standard liver function tests to liver histology. To determine if caffeine clearance is a reflection of liver histopathologic findings.

Technical Approach: 50 subjects will be enrolled in the study. All patients presenting to the GI clinic in whom liver biopsy is indicated will be offered the opportunity to participate. A complete physical examination will be performed, and clinically indicated lab studies will be performed. Exclusion criteria include patient refusal or inability to provide informed consent, contraindication to performance of caffeine clearance (such as drug sensitivity or renal failure), pregnancy, metastatic or primary hepatic malignancy and contraindication to liver biopsy. Specifics are outlined in protocol.

Progress: This is a new study. No reportable data.

Aug 95: Dr. Pfanner has PCSd to DAH. Study is closed for here. He's resubmitting it to open at DAH.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-01 Status: Ongoing

## Stroke Prevention in Atrial Fibrillation III (SPAF III)

Start date: Oct 94	Estimated completion date:
Principal Investigator: Randy E. Modlin, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): Sheri Y. Nottestad, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
Total number of subjects enrolled to date: 18  
Periodic review date: Oct of ea yr Review results: Ongoing

Objective(s): 1. To compare in a randomized clinical trial the efficacy of adjusted-dose warfarin (INR 2.0 - 3.0) to the combination of low-intensity, fixed-dose warfarin (1-3 mg/day) plus aspirin (325 mg/day), enteric-coated) for the prevention of ischemic strokes and systemic emboli (primary events) in AF patients whose rate of primary events would be predicted to be 6.3%/yr during aspirin therapy. 2. To prove that AF patients without risk factors for thromboembolism have a low rate (<3% per year) of primary events during aspirin therapy by a longitudinal cohort study.

Technical Approach: Specifics are outlined in protocol.

Progress: Oct 95: Ongoing - need three more patients for completion.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-05      Status: Ongoing

A Phase II Pilot Study of the Antiemetic Effectiveness of IV Granisetron in Patients Receiving Preparative High Dose Chemotherapy Prior to Autologous Bone Marrow Transplantation

Start date: 28 Sep 94	Estimated completion date:
Principal Investigator: Matthew J. McCarty, M.D.	Facility: BAMC
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): David Stewart, M.D. Scott C. Martin, RPH Svetislava J. Vukelja, M.D. Terry R. Jenkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): (1) To assess the efficacy of single daily doses of intravenous granisetron in preventing nausea and emesis in patients receiving highly emetogenic chemotherapy prior to autologous bone marrow transplantation. (2) To assess patient satisfaction with the antiemetic agent.

Technical Approach: Study population, study plan, treatment regimen, etc. outlined in protocol.

Progress: Oct 95: Due to absence of PI, report will be forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-95-07

Status: Completed

A Double Blind Study Comparing EMLA Cream to Iontophoresis of Lidocaine (Xylocaine) for Painless Induction of Cutaneous Anesthesia.

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Padman A. Menon, M.D.	Facility: BAMC
Department/Service: Medicine/Dermatology	Associate Investigator(s): William J. Grabski, M.D. Lawrence L. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 48

Total number of subjects enrolled to date: 48

Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the effect of EMLA cream versus iontophoresis of 2% xylocaine (lidocaine) with 1:100,000 epinephrine to reduce/alleviate pain and discomfort associated with the needle insertion for injection of local anesthetic.

Technical Approach: 48 healthy volunteers will be invited to participate in the study after obtaining an informed consent. The study will be conducted at the Dermatology Clinic, BAMC. A: Inclusionary criteria - 1. Individuals eligible for military health care including active duty, dependents and retirees; 2. Volunteers will not have taken analgesics 24 hours prior to the study. B: Exclusionary Criteria - 1. Past history of allergies to lidocaine or any amide group; 2. Pregnant or breast feeding females; 3. Children (under 18 years of age).

Progress: Jul 95: Study was completed in Mar 95. No complications noted; no patients dropped out of the study. Study was presented at the 25th Annual Meeting of the American Society for Dermatologic Surgery 5/95. Manuscript has been prepared.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-13 Status: Ongoing

High-Dose Chemotherapy with or without Total Body Irradiation with Autologous Stem Cell Support and Alpha-Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis

Start date: 25 Dec 94	Estimated completion date:
Principal Investigator: Svetislava Vukelja, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To assess the efficacy of fractionated total body irradiation and cyclophosphamide or BCNU, VP-16 and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis, low-grade lymphoma. 2. To assess the feasibility of administration and the therapeutic effect of post-transplant consolidation therapy with alpha interferon in patients who have achieved a complete response to high dose chemo(radio)therapy and ASCT. 3. To assess the prognostic value of serial monitoring of bcl-2 and bcl-1 gene rearrangements as markers of residual lymphoma cells.

Technical Approach: Eligibility criteria, treatment plan, etc, are outlined in protocol.

Progress: Dec 95: One patient placed on study and doing well so far.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-16 Status: Ongoing

## Serum CK Response to Endomyocardial Biopsy

Start date: 17 Jan 95	Estimated completion date:
Principal Investigator: Timothy R. Malinowski, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): Armistead L. Wellford, M.D. David M. Mego, M.D. Nancy Khan, RN Phillip R. Elmore, 1LT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): Determine the response of serum total CK and CK isoenzymes following endomyocardial biopsy.

Technical Approach: To assist in the assessment of a patient presenting with possible ischemic chest pain following endomyocardial biopsy. Patient selection and further specifics are outlined in protocol.

Progress: No update furnished. Annual review will be done in January 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-17 Status: Ongoing

Evaluation of the String Test (Enterotest) for Diagnosing Helicobacter Pylori Infection

Start date: 17 Jan 95	Estimated completion date:
Principal Investigator: Albert Fedalei, M.D.	Facility: BAMC
Department/Service: Medicine/Gastro	Associate Investigator(s): Allan A. Parker, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to evaluate the sensitivity and specificity of the Enterotest for diagnosing H. Pylori infection. Optimization of parameters for test administration to maximize sensitivity and specificity will also be evaluated.

Technical Approach: All patients undergoing diagnostic endoscopy and antral biopsy for H. pylori will be asked to participate. It is anticipated that approximately 100 subjects will be required to achieve statistical significance.

Progress: No report as of this date. Annual review due in Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-22 Status: Ongoing

A Randomized, Multicenter, Investigator-Blind Trial Comparing Intravenous CP-116,517 Followed by Oral CP-99, 219 with Intravenous Ciprofloxacin and Ampicillin Followed by Oral Ciprofloxacin and Amoxicillin for the Treatment of Community Acquired Pneumonia

Start date: 6 Feb 95	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: BAMC
Department/Service: Medicine/Infectious Dis Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of sequential therapy with intravenous CP-116,517 followed by oral CP-99,219 as empiric monotherapy compared to intravenous ciprofloxacin and ampicillin followed by oral ciprofloxacin and amoxicillin in the treatment of patients with community acquired pneumonia which requires initial hospitalization and intravenous therapy. To compare the safety and toleration of CP-116,517 and CP-99,219 to ciprofloxacin and ampicillin/amoxicillin.

Technical Approach: Study population, treatments, patient evaluation visits and further specifics are outlined in protocol.

Progress: No report as of this date. Annual review due in Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-23 Status: Ongoing

Phase I Trial of Crisnatol Mesylate on an Increasingly Prolonged Continuous Infusion Schedule in Patients with Refractory Malignancies

Start date: 1 Aug 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	CIC: 1 Aug 94 IRB: 15 Aug 94 CIRO: 20 Jan 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the maximally tolerated dose and the recommended dose (RD) for subsequent Phase II trials of crisanatol given as a prolonged continuous infusion. To determine dose limiting toxicities (DLTs) of crisanatol, including qualitative and quantitative toxicities, and to define their duration and reversibility. To determine plasma levels which can be achieved and maintained via a continuous infusion. To detect any evidence of antitumor activity.

Technical Approach: Chemistry, eligibility criteria, treatment plan and study procedures are outlined in protocol.

Progress: No report as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-24 Status: Ongoing

A Phase I Trial of Paclitaxel and Gemcitabine in Patients with Refractory Solid Tumors

Start date: 15 Aug 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC/UTHSCSA/CTRC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	CIC: 1 Aug 94 IRB: 15 Aug 94 CIRO: 20 Jan 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To identify the maximum tolerated doses and the dose limiting toxicities of gemcitabine and paclitaxel when administered in combination to patients with refractory solid malignances. To determine the qualitative and quantitative toxicities of the gemcitabine/paclitaxel drug combination. To describe any antitumor activity from combination therapy with gemcitabine and paclitaxel.

Technical Approach: Drugs, patient eligiility, descriptive factors, treatment-drug administration and specific info given in protocol.

Progress: No report as of this date. Annual review due Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-25 Status: Ongoing

Phase II Evaluation of MGBG in Patient with Refractory or Relapsed Non-Hodgkin's Lymphoma Associated with Acquired Immunodeficiency Syndrome

Start date: 15 Aug 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC/UTHSCSA/CTRC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	CIC: 1 Aug 94 IRB: 15 Aug 94 CIRO: 20 Jan 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To estimate the response rate, response duration, and clinical benefit for patients with AIDS-related non-Hodgkin's lymphoma (NHL) treated with MGBG who have previously failed one potentially curative regimen for NHL. To define qualitative and quantitative toxicities of MGBG administered to patients with AIDS related NHL.

Technical Approach: Drug information, staging/histology criteria, patient eligibility, treatment plan, dosage modification and specifics are outlined in protocol.

Progress: No report as of this date. Annual review due Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-26 Status: Completed

A Phase II Study to Evaluate the Combination Chemotherapy Regimen of Irinotecan HCl (CPT-11) Plus Cisplatin in Patients with Inoperable Non-Small Cell Lung Cancer (NSCLC)

Start date: 24 Oct 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC/UTHSCSA/CTRC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	CIC: 3 Oct 94 IRB: 24 Oct 94 CIRO: 10 Jan 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Oct of ea yr Review results: Closed

Objective(s): 1. Is irinotecan in combination with cisplatin effective in the treatment of your cancer? 2. If your cancer does respond to treatment, how long will the response last and will this treatment prolong your life? 3. What are the side effects of irinotecan in combination with cisplatin and how often do they occur? 4. Does treatment with irinotecan in combination with cisplatin improve your quality of life?

Technical Approach: Drug information, patient eligibility, treatment plan, and specifics are outlined in protocol.

Progress: Oct 95: The study has completed accrual, and the activity observed was impressive with numerous responses documented. Toxicity was manageable with modest GI toxicity noted. Trial results are being analyzed as this has a multi-institutional trial including a total of 50 patients. A manuscript is in preparation.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-27 Status: Ongoing

A Phase I Study of the Pharmacokinetics, Safety and Tolerability of Single and Combination Administration of VX-710 in Patients Receiving Single Agent Therapy with Paclitaxel

Start date: 24 Oct 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC/UTHSCSA/CTRC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	CIC: 3 Oct 94 IRB: 24 Oct 94 CIRO: 10 Jan 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the safety and tolerability of VX-710 alone and in combination with paclitaxel. To obtain pharmacokinetic information for various doses of VX-710 administered as a 24 hr infusion alone and concurrently with paclitaxel. To achieve whole blood concentrations of VX-710 in the predicted therapeutically effective range and characterize the pharmacokinetics of the single agent and combination therapy at these doses. To document any antitumor efficacy of VX-710 in combination with paclitaxel.

Technical Approach: Study population, procedures, drug information and specifics outlined in protocol.

Progress: Oct 95: Accrual goes well with this study and several dose escalations have been made per protocol. Toxicity has been acceptable with only modest hematologic reaction observed. The pharmacokinetic data has been analyzed and shows increased levels of paclitaxel as expected. Planned dose increases per protocol will be continued per protocol.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-28 Status: Ongoing

A Phase I Escalating-Dose Study to Evaluate the Safety and Pharmacokinetics of a Five-day Regimen of Intravenous 1843U89 Alone and in Combination with High-Dose Oral Folic Acid

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David Rinaldi, M.D. Miriam Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: Nov of ea yr Review results:

Objective(s): 1. To determine the maximum tolerated dose of five daily doses of intravenous 1843U89 when administered alone and in combination with oral folic acid. 2. To evaluate the safety and describe the toxicity of intravenous 1843U89 alone. 3. To evaluate the safety and describe the toxicity of intravenous 1843U89 and oral folic acid when administered together. 4. To determine the pharmacokinetics of intravenous 1843U89 alone. 5. To determine the pharmacokinetics of intravenous 1843U89 and oral folic acid when administered together. 6. To document any observed antitumor activity of intravenous 1843U89 when administered alone and in combination with oral folic acid.

Technical Approach: Study design, subject selection, dosages, measurements/evaluations, and further details are outlined in protocol.

Progress: Nov 95: Initial accrual to the Phase I 1843 portion of the study is complete with mucosins and dermatitis being the dose-limiting toxicity. Escalation is now proceeding with the addition of folic acid, and thus far, the folic acid has ameliorated the toxicities. Hints of activity have been observed in patients with gastric and colon cancer.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-29 Status: Ongoing

Phase I Study to Determine the Safety of LU 103793 as a 5-Min. IV Infusion Daily X 5 Given Every 3 Weeks to Patients with Malignant Solid Tumors

Start date: 24 Oct 94	Estimated completion date:
Principal Investigator: David A. Rinaldi, M.D.	Facility: BAMC/UTHSCSA
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. Howard Burris, M.D. Miriam Y.J. Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): Purposes are: 1. To determine the maximum tolerated dose of LU 103793 when administered as a single 5-min IV infusion daily x 5, given every 3 weeks in adult patients with solid tumors; 2. To determine the qualitative and quantitative toxic effects of LU 103793 and to study the predictability, duration, intensity, onset and reversibility of the toxic side effects; 3. To propose a safe dose (ie. near MTD) for phase II evaluation; 4. To study the pharmacokinetics of LU 103793 in man at the different dose levels, and to evaluate the rationale for this schedule; 5. To document any possible antitumor activity.

Technical Approach: This is a mono-center, non-randomized, open-label, uncontrolled dose-finding study. Study population, treatment plan/methods, efficacy and safety parameters, study materials and other specifics are outlined in protocol.

Progress: Oct 95: The trial continues per protocol. Substantial hematologic toxicity has been seen at lower dose levels than anticipated, and this trial will close soon. No antitumor activity noted to date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-30 Status: Ongoing

A Phase II Study to Evaluate Alternating Cycles of Irinotecan HCl (CPT-11) and 5-Fluorouracil (5-FU) Plus Leucovorin (LV) in Patients with Metastatic Colorectal Cancer

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC/UTHSCSA
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):  Patrick W. Cobb, M.D. Timothy O'Rourke, M.D. David A. Rinaldi, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To estimate the antitumor activity of alternating cycles of irinotecan (CPT-11) and 5-fluorouracil plus leucovorin (5-FU/LV) in patients with metastatic colorectal cancer who have not received any prior chemotherapy or radiation therapy for their colorectal cancer. 2. To estimate the duration of response, time to treatment failure, and overall survival in this group of patients. 3. To evaluate the qualitative and quantitative toxicities of this drug combination in patients with metastatic colorectal cancer. 4. To evaluate tissue target enzyme activity and expression in order to correlate baseline measurements of four putative molecular markers of chemotherapeutic effect with response to clinical treatment in a subset of patients (N=20).

Technical Approach: Eligibility criteria, treatment plan, dosage modifications and other specifics are outlined in protocol.

Progress: Nov 95: Accrual is proceeding quickly in this multi-institutional trial and remarkable anti-tumor activity has been observed. Toxicities have been manageable, consisting of the expected diarrhea and occasional myelosuppression.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-33 Status: Ongoing

Validation of a Modified Surface Electrode for Sensory Nerve Conduction Testing

Start date: 19 Dec 94	Estimated completion date:
Principal Investigator: Frank Underwood, SP	Facility: AMEDDC&S
Department/Service: Physical Ther Br, AMEDDC&S	Associate Investigator(s):
Key Words:	CIC: 5 Dec 94 IRB: 19 Dec 94 CIRO: 5 Mar 95
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Is the peripheral evoked potential in the sural nerve equivalent when recorded using standard electrodes and a modified electrode?  
 2. Does the use of a modified surface electrode increase the probability of recording a reliable sural nerve response in patients with signs of peripheral neuropathy?

Technical Approach: Study design, hypothesis, description of subjects, experimental design and methods are included in the protocol.

Progress: No report provided as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-37 Status: Completed

Randomized, Double-Blind Study Comparing Stanozolol and Placebo in Patients with Cancer Cachexia

Start date: 15 Aug 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To evaluate the effect of placebo versus stanozolol (STN) given by mouth daily for twelve weeks to determine its effects on weight gain, appetite, anthropometric parameters, protein status (albumin, pre-albumin), performance status, body composition, and quality of life. 2. The second objective is to assess the toxicity of STN at this dosage level.

Technical Approach: Background/rational, drug info, patient selection, treatment plan and detailed specifics are outlined in protocol.

Progress: May 95: Accrual goals have been met. The results are being analyzed and a manuscript is forthcoming.  
 Nov 95: Data analysis is complete and a manuscript has been completed for possible publication.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-38      Status: Ongoing

Phase I Trial to Determine the Maximum Tolerated Dose of Irinotecan Hydrochloride (CPT-11) Using an Every-Other-Week Dosing Schedule in Patients with Advanced Solid Tumor Malignancies

Start date: 19 Dec 95	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC, UTHSCSA
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A Rinaldi, M.D. Miriam Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 4  
Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To determine the maximum tolerated dose of irinotecan when administered every other week to patients with advanced solid tumor malignancies. If neutropenia is the dose-limiting toxicity, a new MTD will be determined with concomitant granulocyte colony stimulating factor (G-CSF). 2. To evaluate the qualitative and quantitative toxicities of irinotecan on an every-other-week schedule in this patient population. 3. To obtain a pharmacokinetic profile of irinotecan and its active metabolite, SN-38 at the doses used on an every-other-week schedule.

Technical Approach: Drug info, eligibility criteria, pretreatment evaluation, treatment plan, dosage modifications and other specifics are outlined in protocol.

Progress: Dec 95: Accrual has proceeded. Diarrhea remains the major toxicity of CPT-11 but 6 manageable with immodium. Significant antitumor activity has been observed in patients with refractory colon cancer.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-39 Status: Ongoing

A Phase I/II Trial of 5-Ethynyluracil (776C85) Plus 5-Fluorouracil in Patients with Solid Tumors

Start date: 18 Apr 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the safety of 776C85 (alone) and the lowest dose of 776C85 which effectively inhibits uracil reductase as defined in section 5.4.1. To determine if the pharmacokinetics of 5-FU in 776C85-treated patients allows five-day treatment. To determine the MTD of 5-FU when co-administered with 776C85. To determine the MTD of 5-FU + leucovorin when co-administered with 776C85, after the MTD of 5-FU in the presence of 7876C85 is reached. To determine the pharmacokinetics of 776C85 with and without 5-FU. To determine the pharmacokinetics of 5-FU (+leucovorin) in combination with 776C85.

Technical Approach: Inclusion/exclusion criteria, treatment plan and specifics are outlined in protocol.

Progress: No report provided as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-46 Status: Ongoing

Chemoimmunotherapy of Metastatic Renal Cell Carcinoma with Interleukin-2, Interferon- $\alpha$ 2B, and 5-Fluorouracil (#IS-L2001)

Start date: 19 Dec 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Patrick W. Cobb, M.D. Timothy J. O'Rourke
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Dec of ea yr Review results:

Objective(s): To evaluate the incidence and severity of adverse events occurring during therapy. Evaluate the complete and partial remission rate. Secondary Objectives: Evaluate the durability of the complete and partial responses. Evaluate the progression-free survival in all patients. Evaluate survival in all patients treated.

Technical Approach: Study design, patient selection, inclusion/exclusion criteria and other specifics are outlined in protocol.

Progress: Dec 95: Accrual goes well in this multi-institutional trial. Several anti-tumor responses have been documented. Toxicity is significant as expected but is manageable, consisting predominantly of flu-like symptoms. Accrual has been proceeding in this multi-institutional trial, and closure is anticipated soon.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-48 Status: Ongoing

A Comparison of Stress Echocardiography, Dobutamine Echocardiography, and Adenosine Sestamibi SPECT Perfusion Imaging for Detection of Coronary Artery Disease in Patients with Left Bundle Branch Block

Start date: 19 Dec 94	Estimated completion date: Dec 96
Principal Investigator: James L. Furgerson, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): David Mego, M.D. Terry Bauch, M.D. Howard Zimring, M.D. Gilberto Sostre, M.D. Douglas Ebersole, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Dec of ea yr Review results:

Objective(s): To compare stress echocardiography, dobutamine echocardiography, and adenosine SPECT perfusion imaging in the detection of coronary artery disease in identical patients with left bundle branch block by a prospective analysis of all modalities in patients followed at BAMC.

Technical Approach: Medical application/status, technical approach and specifics are outlined in protocol.

Progress: Dec 95: Charts for prespective study subjects have been reviewed and approximately 20 suitable candidates have vbeen identified.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-57 Status: Ongoing

Assessment of myocardial viability using the Doppler flo-wire and low dose dobutamine

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: William A. Rollefson, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To assess myocardial viability in patients recently diagnosed with myocardial infarction and resultant left ventricular dysfunction using the Doppler flo wire during low dose dobutamine infusion.

Technical Approach: To determine if coronary revascularization at the time of the initial catheterization dysfunction is indicated by using the doppler flo wire and low dose IV dobutamine to predict myocardial viability. By utilizing the doppler flo-wire to predict myocardial viability the patient will avoid further invasive catheterization procedures, costly viability testing, and several inpatient hospital days.

Progress: No report furnished as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-71 Status: Ongoing

A Phase I Study to Evaluate Orally-Administered Irinotecan HCl (CPT-11) Given Daily x 5 Every 3 Weeks in Patients with Refractory Malignancies

Start date: 30 Jan 95	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Patrick W. Cobb, M.D. Timothy J. O'Rourke, M.D. David a. Rinaldi, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To determine the maximally-tolerated dose (MTD) and the dose-limiting toxicity of irinotecan when administered orally, once a day for five consecutive days. 2. To characterize the safety profile of irinotecan when administered orally in this manner. 3. To characterize the single and multiple dose pharmacokinetics of irinotecan and its active metabolite, SN-38. 4. To detect any evidence of antitumor activity.

Technical Approach: As outlined in the protocol.

Progress: No report furnished as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-73 Status: Ongoing

A randomized, single blind study to compare the cost and efficacy of topical calcipotriene (Dovonex) with that of topical 5-fluorouracil (Efudex) for the treatment of psoriasis

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Dirk M. Elston, M.D.	Facility: BAMC
Department/Service: Medicine/Dermatology Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the cost and efficacy of two drugs used for the treatment of chronic plaque-type psoriasis.

Technical Approach: Approximately 68 adult patients with stable plaque-type psoriasis involving less than 30% of body surface area (estimated using the "rule of 9's") will be randomized to receive topical treatment with either calcipotriene or 5-FU. All lesions present at baseline will be treated, except those on the face and genitalia. Baseline complete blood count and chemistry profile (M1) will be obtained. Patients with hypercalcemia or neutropenia will not be enrolled. Women of child bearing potential will not be enrolled unless they are using two effective forms of birth control. A negative serum HCG will be obtained prior to initiation of therapy, and therapy will be started on the second or third day of the following menstrual period. Prior to beginning treatment, each lesion will be outlined on plastic wrap, and the area calculated.

Progress: No report furnished as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-75 Status: Ongoing

Regression of Barrett's Esophagus After Nissen Fundoplication

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Philip E. Tanner, M.D.	Facility: BAMC
Department/Service: Medicine/Gastroenterology Svc	Associate Investigator(s): Richard Shaffer, M.D. Shailesh Kadakia, M.D. Johnny Alvarez, M.D. R. Russell Martin, M.D. Spencer Root, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): This is a prospective study designed to determine if a regression in the length of Barrett's esophagus relative to a tattoo marking occurs after Nissen fundoplication surgery.

Technical Approach: The hypothesis to be tested is that the length of Barrett's esophagus regresses or shortens after anti-reflux surgery (Nissen fundoplication). Those patients with endoscopic and biopsy-proven Barrett's esophagus who are referred for Nissen fundoplication will be eligible for the study. Thirty patients will be enrolled.

Progress: No report furnished as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-76 Status: Ongoing

Concentrations of methane and hydrogen in colonic gas during colonoscopy after preparation of the colon with Phospho-soda buffered oral saline laxative solution

Start date: 6 Feb 95	Estimated completion date:
Principal Investigator: Timothy P. Pfanner, M.D.	Facility: BAMC
Department/Service: Medicine/Gastroenterology Svc	Associate Investigator(s): Allan Parker, D.O. Michael Riel, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To measure the concentrations of Hydrogen and Methane in the Colon during colonoscopy after the Colon is lavaged with Fleets Phospho-soda buffered oral saline laxative. This is to determine if there is any explosive potential during electrocautery in patients who have undergone oral phospho-soda in preparation for colonoscopy.

Technical Approach: 10-30 patients in whom colonoscopy is indicated and who have utilized Fleet Phospho-soda buffered oral saline laxative solution for colon cleansing will be enrolled into this pilot study. A complete physical examination and clinically indicated lab studies shall be performed by the examining physician.

Progress: No report furnished as of this data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-80 Status: Ongoing

Coronary Blood Flow Hemodynamics in Patients with Left Bundle Branch Block

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Terry D. Bauch, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): Howard J. Zimring, M.D. Miguel A. Campos, M.D. Douglas G. Ebersole, M.D.
Key Words:	David M. Mego, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Compare the Coronary Flow Reserve (CFR) of the Left Anterior Descending (LAD), First Septal Perforator (FSP) and Circumflex (CFX) coronary arteries in patients with isolated Left Bundle Branch Block (LBBB).  
 2. Compare the CFR of the LAD in these patients with normal controls.  
 3. Compare the coronary flow response of the LAD, FSP, and CFX to heart rate and Dobutamine stimuli in patients with LBBB.

Technical Approach: Include patients over 18 years old with isolated LBBB who will undergo cardiac catheterization for clinical indications. Exclusions and further specifics outlined in protocol.

Progress: No report furnished as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-88 Status: Ongoing

Use of Intravenous Erythromycin in Acute Upper Gastrointestinal Hemorrhage

Start date: 5 Jun 95	Estimated completion date:
Principal Investigator: James K. Howden, M.D.	Facility: BAMC
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh Kadakia, M.D. Albert Fedalai, M.D. Charles Farrington, M.D. Timothy Pfanner, M.D. Michael Reil, D.O. & Philip Tanner, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To investigate the efficacy of intravenous erythromycin, a promotility agent in emptying the stomach and duodenum of blood and clots, to facilitate an adequate endoscopic examination in the acute upper gastrointestinal hemorrhage situation. Erythromycin will be compared to placebo in a study population of all adult patients admitted to the Med Intensive Care Unit with an UGI hemorrhage and oral gastric lavage positive for coffee ground, clots or bright red blood. Patients will be randomized and both patients and physicians will be blinded to the treated and placebo groups.

Technical Approach: Outlined in protocol, including experimental design, data collection, statistical analysis, etc.

Progress: No report furnished as of this date.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-90 Status: Ongoing

Coronary Blood Flow Hemodynamics in Normal Patients Measured with the Doppler Flo-Wire

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Howard J. Zimring, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology Svc	Associate Investigator(s): Miguel A. Campos, M.D. Douglas G. Ebersole, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To obtain normal indices of coronary blood flow velocity, diastolic to systolic velocity ratio, and coronary vascular reserve utilizing the Doppler flo-wire during varying heart rate/blood pressure conditions, and IV dobutamine infusion.

Technical Approach: Medical application, status, methods, statistics/data analysis and specifics are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-93 Status: Ongoing

Phase I Trial of Gemcitabine Plus Hydroxyurea in Patients with Refractory Solid Tumors

Start date: 19 Dec 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Dec of ea yr Review results:

Objective(s): Primary objective is to determine the MTD and DLT of gemcitabine and hydroxyurea combination therapy when administered to patients with refractory solid tumors. Secondary objectives are: 1. To determine the qualitative and quantitative toxicities of the gemcitabine and hydroxyurea combination therapy. 2. To describe any antitumor activity from gemcitabine and hydroxyurea combination therapy. 3. To measure the activity of the enzyme ribonucleotide reductase in tumor cells of patients receiving gemcitabine and hydroxyurea combination therapy. 4. To measure the pharmacokinetic parameters of gemcitabine and hydroxyurea.

Technical Approach: Details outlined in protocol.

Progress: Dec 95: This trial is nearing completion and has gone well. Toxicities are predominantly brief myelosuppression, neutropenia and thrombocytopenia. Hints of toxicity have been observed in patients with lung cancer and pancreatic cancer.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-95 Status: Ongoing

Assessment of myocardial viability using the Doppler flow-wire and Positron Emission Tomography in chronic coronary artery disease patients

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Howard J. Zimring, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): John Walsh, M.D. Bernard J. Rubal, Ph.D. Douglas G. Ebersole, M.D. Alfred C. Gorman, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To assess myocardial viability in patients with chronic coronary artery disease and resultant left ventricular dysfunction using the Doppler flow wire during low dose dobutamine infusion and compare Doppler flow wire viability to PET scan results.

Technical Approach: To determine if coronary revascularization at the time of catheterization of patients with chronic coronary artery disease and left ventricular (LV) dysfunction is indicated by using the Doppler flow wire and low dose IV dobutamine to predict myocardial viability the patient will avoid costly alternative viability testing and several inpatient hospital days.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-96 Status: Ongoing

Golytely Bowel Prep - Does Cisapride Help?

Start date: 9 Jun 95	Estimated completion date:
Principal Investigator: Charles A. Farrington, M.D.	Facility: BAMC
Department/Service: Medicine/Gastro	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To investigate the use a cisapride as a bowel preparation premedication, to see if it can improve patient tolerance of Golytely, and to see if it improves bowel cleansing.

Technical Approach: One hundred fifty adult patients (age 18-80) undergoing colonoscopy for routinely accepted indications will be randomized in a double-blind manner to a placebo group or a treatment group using 20 mg. of cisapride as a premedication prior to golytely bowel lavage. patients with suspected bowel obstruction will be excluded. Otherwise all patients will be included, regardless of underlying medical condition or suspected bowel pathology.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-99 Status: Ongoing

A Multicenter Randomized Phase III Study of Docetaxel (RP 56976, Taxotere) versus Best Supportive Care in Patients with Non-Small Cell Lung Cancer Previously Treated with Platinum-Based Chemotherapy

Start date: 5 Jul 95	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): Primary: To evaluate survival in patients with non-small cell lung cancer (NSCLC) previously treated with platinum-containing chemotherapy receiving either docetaxel or best supportive care.  
 Secondary: To compare the quality of life of patients in each treatment arm; and determine the safety and efficacy (response rate, response duration) of docetaxel administered as an one-hour IV infusion every 21 days in a randomized setting.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-100 Status: Ongoing

A Phase I Trial and Pharmacokinetic Study of the Sequential Administration of Carmustine (BCNU) and Temozolomide in Patients with Advanced Refractory Solid Tumors or Refractory Lymphoma

Start date: 24 May 95	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): To estimate the maximum tolerated dosage and the dosage for Phase II trials for oral temozolomide in combination with BCNU in patients with advanced cancer and lymphoma. To characterize the dose-limiting toxicity and other toxicities of this combination when either temozolomide or BCNU is give first. To characterize the pharmacokinetics of temozolomide and MTIC on these schedules. To identify any preliminary evidence of anticancer activity in treated patients. To determine ATase levels in mononuclear cells in patients treated on these schedules.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-101 Status: Ongoing

An Open-label Multicenter Trial to Evaluate the Safety and Effectiveness of Various Treatment Durations of Terbinafine in patients with Onychomycosis of the Toenails

Start date: 25 Jul 95	Estimated completion date:
Principal Investigator: Richard A. Keller, M.D.	Facility: BAMC
Department/Service: Medicine/Dermatology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and effectiveness of 12, 18, or 24 weeks of therapy with 250 mg/day of terbinafine in patients with onychomycosis of the toenails. Secondary objective is to evaluate the epidemiologic aspects of toenail onychomycosis in the US as well as changes in the quality of life associated with oral terbinafine in the treatment of onychomycosis.

Technical Approach: Study overview, materials/methods and specifics are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-108 Status: Ongoing

Treatment IND of Gemzar (Gemcitabine) for Patients with Pancreatic Cancer

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: David A. Rinaldi, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. Howard Burris, M.D. Miriam Y.J. Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): Primary: To provide for the treatment of patients with locally advanced (Stage IIC or III) or metastatic (Stage IV) pancreatic cancer (Attachment JHEW (c).1). Patient access to gemzar through the Treatment IND will occur while the FDA reviews the safety and efficacy as described in the New Drug Application (NDA) for Gemzar and considers the drug for commercial release.

Secondary: To collect further basic safety and efficacy data.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-110 Status: Ongoing

An Open-Label, Multicenter, Randomized, Phase III Study of Hycamtin (Topotecan) as Single Agent, Second-Line Therapy (Administered Intravenously as Five Daily Doses Every 21 Days) Vs Second-Line CAV in Patients with SCLC Who Have Relapsed at Least Three Months After Completion of First-Line Therapy

Start date: 1 Aug 95	Estimated completion date:
Principal Investigator: Yvette Atkins, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Howard Burris, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Primary: To evaluate the response rate and response duration in patients with local or extensive small cell lung cancer who relapsed at least three months after completion of prior chemotherapy, following treatment with single agent Hycamtin<sup>TM</sup> administered as five daily 30-minute infusions every 21 days, or with a combination of cyclophosphamide, doxorubicin and vincristine (CAV) administered once every 21 days.  
 Secondary: To evaluate the time to response, time to progression, survival and symptoms of disease in patients with local or extensive SCLC treated with Hycamtin<sup>TM</sup> or with CAV administered on these schedules. To evaluate the qualitative and quantitative toxicities of Hycamtin<sup>TM</sup> and of CAV administered on these schedules.

Technical Approach: Details are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-111 Status: Ongoing

A Five-Year Observational Study to Evaluate Clinical Response and recurrence Rate in the Treatment of Basal Cell Carcinoma with Fluorouracil/Epinephrine Injectable Gel

Start date: 1 Aug 95	Estimated completion date:
Principal Investigator: William J. Grabski, M.D.	Facility: BAMC
Department/Service: Medicine/Dermatology	Associate Investigator(s): Lawrence L. Anderson, M.D. Mark Welch, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Primary: 1. To describe the recurrence rate 12 months after treatment in those patients with no clinical evidence of disease at Month 3 Follow-up. 2. To describe the clinical response rate of treatment with 0.5 mL 5-FU/epi injectable gel when administered three times weekly for 2 weeks in patients with basal cell carcinoma. 3. To evaluate the safety of the fluorouracil/epinephrine injectable gel when administered as described above. Secondary: 1. To describe the annual recurrence rate for up to 5 years after treatment. 2. To assess the cosmetic result of treatment when administered as described above. 3. To evaluate the safety and efficacy of treatment in collagen skin test positive patients. 4. To determine collagen antibody values for each patient.

Technical Approach: Specifics are outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-113      Status: Ongoing

CARES Study Cardiac Risk Evaluation with Exercise Echocardiography Stress Testing

Start date: 06 Mar 95	Estimated completion date:
Principal Investigator: Sheri Y. Nottestad, M.D.	Facility: BAMC
Department/Service: Medicine/Cardioogy	Associate Investigator(s): James Gilman, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the prognostic value of symptom-limited maximal exercise testing with stress echocardiography in coronary artery disease, specifically in patients with chronic stable angina.

Technical Approach: Details are outlined in protocol

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-114 Status: Completed

Irinotecan (CPT-11) Protocol for Named Patients with 5-Fluorouracil-Refractory Colorectal Cancer at Established Trial Sites

Start date: 31 Jul 95	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy J. O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David Rinaldi, M.D. Miriam Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To allow for the use of irinotecan (CPT-11) in patients with advanced 5-FU refractory colorectal carcinoma who do not qualify for currently active irinotecan protocols, at institutions which are experienced in the use of irinotecan.

Technical Approach: Specifics are outlined in protocol.

Progress: Results are being analyzed and a manuscript is forthcoming.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-115 Status: Ongoing

Multicenter Trial of Oral Ursodeoxycholic Acid vs Combination Ursodeoxycholic Acid Plus Low Dose Oral Pulse Methotrexate Therapy for Primary Sclerosing Cholangitis

Start date: 1 Jul 95	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: BAMC
Department/Service: Medicine/Gastro	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): Purpose of this study is to compare the effectiveness of two different forms of medical therapy, methotrexate and ursodeoxycholid acid (UDCA) in altering the progression of primary sclerosing cholangitis (PSC).

Technical Approach: Details outlined in protocol.

Progress: No report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-118 Status: Ongoing

A Phase I Study of NSC 655649 Given by Bolus Infusion Every 21 Days

Start date:	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc Svc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Miriam Atkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Oct of ea yr Review results:

Objective(s): 1. To evaluate the qualitative and quantitative toxicities of NSC 655649 when administered as a bolus infusion every 21 days. 2. To characterize the pharmacokinetic parameters of NSC 655649. 3. To assess any antitumor effects which might be observed in this initial trial of NSC 655649 in patients with refractory malignancies.

Technical Approach: Experimental design/methods; subject population; recruitment/consent procedures and further specifics are outlined in protocol.

Progress: Oct 95: This trial has not yet begun accrual as drug availability was a problem. A supply has now been delivered and it is anticipated that accrual will begin the last week of Oct 95.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-120 Status: Ongoing

Utility of Digital Acoustic Cardiography for the Evaluation of Heart Murmurs

Start date: 11 Aug 95	Estimated completion date:
Principal Investigator: Terry D. Bauch, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): Bernard J. Rubal, PhD James Bulgrin, BSEE
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Establish criteria to differentiate benign from pathologic murmurs in adults using Digital Acoustic Cardiography (DAC). 2. Determine the accuracy of DAC for the differentiation of such murmurs in both active duty and retiree/dependant populations. 3. Determine the accuracy of DAC for detecting clinically significant changes in stenotic aortic valve jet velocity in adults.

Technical Approach: Subjects, Methods, Data Collection, Statistical Analysis and further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-122 Status: Ongoing

Letrozole (CGS 20267) Comparison of Two Doses (0.5mg and 2.5mg) of Letrozole (CGS 20267) Versus Megestrol Acetate in Postmenopausal Women with Advanced Breast Cancer - Protocol 02

Start date: 8 Aug 95	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): Primary: To compare the anti-tumor efficacy, as evaluated by the primary variable of objective response rate, and the secondary variables of duration of response, time to treatment failure (TTF), time to progression (TTP) and time to death among the three treatment arms (daily doses of 0.5 mg letrozole, 2.5 mg letrozole or 40 mg megestrol acetate q.i.d.).  
 Secondary: 1. To compare the tolerability and toxicity of daily doses of 0.5 mg letrozole, 2.5 mg letrozole and 40mg megestrol acetate q.i.d. 2. To assess information on population pharmacokinetics including evaluation of trough estrogen levels during treatment with daily doses of 0.5 mg and 2.5 mg letrozole.

Technical Approach: As outlined in the protocol.

Progress: No report available as of this date. Annual review due Aug 96.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-124 Status: Ongoing

Phase I Trial of Pivaloyloxymethylbutyrate (AN-9) as a 6 Hour Continuous Infusion Daily for 5 Days

Start date: 14 Aug 95	Estimated completion date:
Principal Investigator: David A. Rinaldi, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): Primary: To determine the maximum tolerated dose (MTD) of AN-9 when administered as a 6 hour continuous infusion daily for 5 days. The modified continual reassessment method for dose escalation will be employed. The maximum dose will be 3.90g/m<sup>2</sup>/6hr. To determine the qualitative and quantitative toxicities and reversibility of toxicities from AN-9 administered in this fashion.

Technical Approach: Specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-125 Status: Ongoing

A Double-Blind, Randomized, Phase 3, Multicenter Study of Suramin and Hydrocortisone Versus Hydrocortisone and Placebo in the Treatment of Patients with Metastatic, Hormone Refractory Prostate Carcinoma (Stage D2) (Protocol 1003-01)

Start date: 14 Aug 95

Estimated completion date:

Principal Investigator:  
Timothy J. O'Rourke, M.D.

Facility:  
BAMC

Department/Service:  
Medicine/Hem-Onc

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Determine suramin's effect on pain, performance status, PSA, disease response, quality of life and survival in patients with hormone-refractory prostate carcinoma (2) To evaluate the safety of suramin.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-128 Status: Ongoing

An Open Label Study to Evaluate the Effectiveness of 1,25 Dihydroxy Vitamin D<sub>3</sub> (ROCALTROL) in Patients Who Have Limited or Diffuse Systemic Sclerosis

Start date: 17 Aug 95	Estimated completion date:
Principal Investigator: Jeffrey Stiles, M.D.	Facility: BAMC
Department/Service: Medicine/Dermatology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To stop the evolution of, and hopefully reverse the overproduction of collagen by fibroblasts as measured by clinical criteria.

Technical Approach: 1,25 dihydroxy vitamin D<sub>3</sub> is an FDA approved medication in routine use with indications for treatment of hypocalcemia in patients undergoing renal dialysis and for treatment of hypoparathyroidism. 1,25 dihydroxy vitamin D<sub>3</sub> has been used in 3 foreign studies to treat systemic sclerosis (21 patients) and localized scleroderma (7 patients).<sup>5,6,7</sup> The results have been promising and no adverse effects have been noted.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-130 Status: Ongoing

A Phase II, Placebo-Controlled, Multicenter Study of TLC C-53 as an Adjunct to Thrombolytic Therapy in Patients with Acute Myocardial Infarction

Start date: 5 Sep 95	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: BAMC
Department/Service: Medicine/Cardiology	Associate Investigator(s): Kevin Rogers, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of TLC C-53 versus placebo in attaining TIMI (Thrombolysis in Myocardial Infarction) 3 coronary blood flow when given to patients with acute myocardial infarction \*MI) who are to receive tissue-plasminogen activator.

Technical Approach: Design, type of patients, exclusion criteria and further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-136 Status: Ongoing

A Phase II Study to Evaluate a 5-Day Regimen of Oral 5-Fluorouracil (5FU) Plus 776C85 With or Without Leucovorin for the Treatment of Patients with Metastatic Colorectal Cancer

Start date: 26 Sep 95	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Patrick W. Cobb, M.D. Timothy J. O'Rourke, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To evaluate the safety and efficacy of 5-day oral 5-FU given in combination with 776C85 with or without leucovorin in the treatment of patients with previously untreated metastatic colorectal cancer. 2. To evaluate the safety and efficacy of 5-day oral 5-FU and 776C85 with or without leucovorin in the treatment of patients with metastatic colorectal cancer refractory to 5-FU plus leucovorin. 3. To obtain preliminary data on whether 5-FU resistance type (primary versus acquired) affects the antitumor activity of 5-FU plus 776C85. 4. To evaluate the effect of 5-day oral 5-FU/776C85 and 5-day oral 5-FU/776C85 plus leucovorin on quality of life. 5. To evaluate the incremental utility of the CR38, a site-specific QOL module designed to supplement the C30, the core QOL questionnaire.

Technical Approach: Further specifics are outlined in the protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-139 Status: Ongoing

Do alveolar macrophages from emphysematous patients produce increased levels of proteases or cause decreased levels of antiproteases?

Start date: 10 Oct 95	Estimated completion date:
Principal Investigator: Daniel R. Ouellette, M.D.	Facility:
Department/Service: Medicine/Pulmonary Med	Associate Investigator(s): Gerald Merrill, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To investigate the importance of alveolar macrophages and substances that they produce or secrete in the development of emphysema in people who smoke cigarettes. The specific substances to be the subject of this project are previously identified cysteine proteases that have elastolytic properties and peroxidase activity, which can lead to decreased levels of antiproteases. This will be a prospective study involving specimens isolated by bronchoalveolar lavage from about 50 patients and controls with a history of smoking and chronic respiratory illness. .... Results from these assays will be correlated with patient pulmonary function to discover if increased elastolytic activity or peroxidase activity is associated in an incremental fashion with increased severity of obstructive airway disease.

Technical Approach: This investigation is expected to demonstrate that alveolar macrophages isolated from patients with COPD contain a cysteine protease whose activity when quantitated, correlates directly with the degree of airflow obstruction that these patients have. Also expect to demonstrate that oxidase or peroxidase activity of intact macrophages correlates directly with the degree of airflow obstruction.

Progress: No report available as of this date. Annual review due Oct 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-141 Status: Ongoing

Autologous Granulocyte Infusions as Supportive Therapy in Breast Cancer  
Patients Receiving High Dose Chemotherapy with Stem Cell Support

Start date: 1 Aug 95	Estimated completion date:
Principal Investigator: Rickey Myhand, M.D.	Facility: BAMC
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Joseph J. Stephenson, M.D. Svetislava J. Vukelja Gerald Merrill, PhD William Wortham, M.D. Scott Martin, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): Metastatic breast cancer is an incurable disease. Although systemic chemotherapy and hormonal therapy may prolong survival and palliate symptoms for years, most patients with metastatic breast cancer will eventually die of their illness. Recent efforts to improve upon survival using high dose chemotherapy with autologous stem cell support have been widely published and applied. Although approx 20% of patients with metastatic breast cancer treated in this manner appear to be longterm disease-free survivors, the overall survival benefit of this treatment modality compared with conventional dose chemotherapy is uncertain. At this time, high dose chemotherapy with autologous stem cell support for the treatment of metastatic breast cancer is investigational, and randomized trials addressing the benefit of this therapy are ongoing. The mortality associated with this approach is 5-10%. Despite recent advances in supportive care with the use of blood product is still infection. During the period of obligate neutropenia after high dose chemotherapy, virtually all patients suffer from fever necessitating the use of broad spectrum antibiotics.

Technical Approach: Further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-12 Status: Terminated

Title: Intravenous Site Location and Patency Among Pediatric Patients Less Than One Year Old

Start date: Oct 93	Estimated completion date:
Principal Investigator: Glenn R. Fernandes, AN	Facility: Reynolds ACH & Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): Roger Anderson, AN Patti Vincent, AN Peggy Rice, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the relationships among four traditional IV site locations and patency in pediatric patients less than one year old.

Technical Approach: The hypothesis, variables, sampling plan, design, methods and detailed specifics are outlined in protocol.

Progress: This is a new study. There is no data to report.  
 Oct 95: PI has PCSd, study never started.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-14 Status: Ongoing

Title: Computer Simulation Modeling Applied to Capacity Management Decision Making in a Pediatric Ambulatory Clinic

Start date: Oct 93	Estimated completion date:
Principal Investigator: James D. Odom, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): Lee W. Richard, AN
Key Words: consumption, utilization, optimal capacity decision, computer simulation, time-series design	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Oct of ea yr Review results:

Objective(s): 1. To identify those factors that influence resource consumption and utilization in an ambulatory pediatric clinic; and 2. To develop and test a model of optimal capacity decision making through application of computer simulation. Using a time-series design with repeated measurements process, this study will be conducted in two phases. During Phase I, aim 1 will be addressed. During Phase II, a model that can be used for effective capacity management decisions will be developed and tested.

Technical Approach: Design, study site, procedure, computer simulation software, human subjects and other specifics are outlined in protocol.

Progress: The simulation model is essentially complete. Final adjustments being made.

Oct 95: Study is nearing completion; final report forthcoming before end of year.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-145 Status: Ongoing

Title: The Addition of a Sport Psychology Component to a Childbirth Education Curriculum and Its Effect on Obstetric Outcome

Start date: 20 Sep 94	Estimated completion date:
Principal Investigator: Mara D.H. Smith, MEd, CCE	Facility: Brooke Army Medical Center, Texas
Department/Service: Community Health Nursing	Associate Investigator(s): B. Deeter, LTC Jean M. Johnson, PhD, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 48  
Total number of subjects enrolled to date: 48  
Periodic review date: Sep of ea yr Review results:

Objective(s): To examine the relationship between the addition of sport psychology techniques to a standard childbirth education curriculum and obstetric outcome. The study will examine the outcomes of two groups of patients: a control group of primiparas who attend childbirth education classes, and receive the standard childbirth education curriculum and an experimental group who attend childbirth education classes and receive the standard childbirth education curriculum with the addition of a sport psychology component including techniques to be utilized during labor and delivery. The proposed study will attempt to answer the following question: (1) Does the addition of sport psychology techniques to a standard childbirth education curriculum effect obstetric outcome as measured by duration of labor? (2) Does the addition of sport psychology techniques to a standard childbirth education curriculum effect obstetric outcome as measured by the use of analgesia and anesthesia?

Technical approach: 1. Participants who receive the sport psychology component will have shorter labors than those who do not receive this component. 2. Participants who receive the sport psychology component, overall, will use less analgesia and anesthesia than those who do not receive this component.

Progress: Aug 95: Data collection completed - data being analyzed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-03 Status: Ongoing

Evaluation of a structured physical fitness program for pregnant soldiers: Effects on weight gain, blood pressure, lost duty time, length of labor, infant birth weight, and score on the first Army Physical Fitness Test (APFT) post delivery

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Elizabeth Wanersdorfer, AN, MSN	Facility: BAMC/FAMC
Department/Service: Nursing	Associate Investigator(s): Elizabeth Hill, DNSc, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100  
Total number of subjects enrolled to date: 100  
Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether pregnant soldiers participating in a structured exercise program will have less weight gain, less change in blood pressure, shorter length of labor, higher birth weight babies, less lost duty time, and better ability to pass their first physical fitness test than do pregnant soldiers who do not participate in a structured program. The long term objective is the development of military policy for physical training for pregnant soldiers, contributing to healthier soldiers, healthier babies, and improved military readiness.

Technical Approach: Study Design, Medical Application, Plan and further details are outlined in protocol.

Progress: Nov 95: Enrollment is taking longer than originally anticipated but the goal should be met. Basic data has been loaded into the computer but no significant results are available at this time. At this time have sixty-six per cent of the total enrollment. Three have had to drop out of the study for reasons unrelated to the study. Data will not be analyzed until the study is completed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-14 Status: Ongoing

Alternative Pain Therapy & Anxiolysis in Surgery

Start date: 13 Jan 95	Estimated completion date:
Principal Investigator: Maureen Reilly, AN	Facility: BAMC
Department/Service: Nursing	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To examine an alternative method for sedating patients while the ophthalmologist is anesthetizing the eye. This method of sedation has been studied in a smaller number of patients in another project. This project will be done on approximately 116 patients.

Technical Approach: Study design/method, specific aim, background and significance and further details are included in protocol.

Progress: No report available as of this date. Annual review due Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-35 Status: Ongoing

## Identification of Family Strengths and Needs Using the Q-Sort Process

Start date: 1 Feb 95	Estimated completion date:
Principal Investigator: Patrice E. Chandler, AN	Facility: BAMC/BAMC
Department/Service: Nursing	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): Approximately 30 to 40 parents or sets of parents will be recruited who meet inclusion criteria (i.e., have an infant(s) currently in the NICU for greater than 10 days duration whose diagnosis meets the criteria for an IFSP under the guidelines outlined in PL99-457). The optional nature of participation will be stressed in describing the project to parents.

Technical Approach: The following demographic information will be collected: maternal data, infant data, sibling data, family socioeconomic data and hospitalization data.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-40 Status: Ongoing

An Exploration of Quality of Life Experienced by People with Cancer

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Linda H. Yoder, AN	Facility: Brooke Army Medical Center
Department/Service: Nursing	Associate Investigator(s): Timothy O'Rourke, M.D. Sandra J. Begley, ANC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): In the last decade there has been a proliferation of new drugs and strategies for intensifying the treatments used to combat cancer. These aggressive treatment strategies also have led to increasing toxicities experienced by patients. Often, cancer therapies are evaluated solely on the basis of increased survival. It is critical that outcomes for cancer patients move beyond morbidity and mortality statistics to include information about quality of life during and after treatment.

Technical Approach: Study design, methods and specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-41 Status: Ongoing

A Comparative Study of Parental Stress in the Neonatal Intensive Care Unit

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Patrice Chandler, AN	Facility: BAMC
Department/Service: Nursing	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): The specific aims of this study of parents with preterm infants requiring neonatal intensive care, are to determine: 1. levels of parental psychosocial stress during the initial phase of neonatal intensive care experience; 2. effectiveness of a cognitive intervention on parental knowledge about the care of the preterm infant; 3. effectiveness of a cognitive intervention on parental psychosocial stress during the neonatal intensive care experience; 4. effectiveness of a cognitive intervention on parent-infant interaction at the time the infant meets discharge criteria; 5. effectiveness of a cognitive intervention on parental psychosocial stress at the time the infant meets discharge criteria.

Technical Approach: Research design and specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Mar 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-42 Status: Ongoing

Determinants of Health-Promoting Behaviors of Patients with Chronic Stable Angina

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Nancy S. Hodge, AN	Facility: BAMC
Department/Service: Nursing	Associate Investigator(s): Nancy Khan, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Note: This study is a companion study to "Stress Echocardiography for Cardiac Risk Stratification of Patients with Stable Chest Pain" by MAJ Sheri Y. Nottestad, MC, Cardiolgoy Svc; approved in Feb 95.

Objective(s): 1. Describe the perceived control of health beliefs, health-promoting behaviors, and perceived health status of patients with chronic stable angina enrolled in the Chronic Angina Risk-stratification with echocardiography stress (CARES) study. 2. Examine the relationships between perceived control of health beliefs, health-promoting behaviors, perceived health status results of the stress echocardiography testing, and major cardiac events in patients with chronic stable angina.

Technical Approach: Methods and specific details are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-77 Status: Ongoing

Pressure Ulcers: Patient Outcomes on a Kinair Bed or EHOB Mattress

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Gladys A. Cobb, CPT, AN	Facility: BAMC
Department/Service: Nursing Dept	Associate Investigator(s): Linda H. Yoder, BSN MSN MBA PhD Gerald Harrington, Jr., BS M.D. Sondra Perdue, BA MS PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To compare a low air loss, pressure relieving rental bed to a waffle pressure relieving air mattress overlay. Subjects will consist of patients considered to be at high risk for pressure ulcer development. More specifically, the following research questions will be addressed: 1. What is the demographic profile of the patient at high risk for pressure ulcer development in a large military acute care setting? 2. Is there a difference in the number of pressure ulcers or the seriousness of pressure ulcers that develop among high risk patients when Kinair low air loss specialty beds are used compared to EHOB waffle air mattress overlays? 3. Is there a difference in length of stay, related to pressure ulcers, among high risk patients when placed on the Kinair bed compared to the EHOB waffle air mattress? 4. Is there a difference i cost expenditure related to pressure ulcer development when Kinair low air loss specialty beds compared to EHOB waffle air mattresses are used?

Technical Approach: Background/significance, definition/physiology, risk factors, research design/methods and further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-78 Status: Ongoing

An exploration of Quality of Life experienced by People with Chronic Obstructive Pulmonary Disease

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Susan E. Anderson, AN BSN MSN	Facility: BAMC
Department/Service: Nursing Dept	Associate Investigator(s): Linda H. Yoder, AN BSN MSN MBA PhD Sondra T. Perdue, BA MS PhD Anne Coscarelli, BA MA PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): The life expectancy of most adult Americans has markedly increased with the advent of advanced medical technology. A significant consequence of the increase in longevity is a shift in the nature of prominent diseases from acute chronic. There has been a growing awareness of the inadequacy of the traditional morbidity and mortality data in reflecting health status in the chronic patient population. we can no longer afford to assume that medical interventions are producing desired result. The focus of care of the chronically ill has shifted from cure to care and rehabilitation. As patients with chronic and disabling diseases are offered a variety of treatment choices, the challenge becomes how to choose an option that provides the greatest quality of life. In certain diseases, such as chronic obstructive pulmonary disease, quality of life may be the most important health outcome to consider.

Technical Approach: Further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-79 Status: Ongoing

## A Comparison of Two Totally Implanted Venous access Devices

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Lilly J. Noble, RN MSN AN	Facility: BAMC
Department/Service: Nursing Dept	Associate Investigator(s): Linda Yoder, RN MBA PhD Robert R. Martin, BS MD Gale E. Mancoff, ADN Timothy O'Rourke, BS MS MD Sondra Perdue, BA MS PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): The overall aim of this study is to use clinical research to problem solve a recurrent quality assurance issue concerning the LifePort implantable venous access device. The specific aim is to evaluate an implanted venous access device (IVAD) with a revolutionary new design, the OmegaPort by Norfolk Medical, compared to the standard IVAD, the LifePort by Strato/Infusaid, currently in use. To this end the following hypotheses have been generated: 1. The OmegaPort will have a lower incidence of complications than the LifePort. 2. Over a period of nine months, total costs associated with the OmegaPort will be less than total costs associated with the LifePort. 3. Patient satisfaction regarding the IVAD will be higher for the OmegaPort.

Technical Approach: Further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-81 Status: Ongoing

An Exploration of Quality of Life Experienced by People with Congestive Heart Failure

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Nancy S. Hodge, RN	Facility: BAMC
Department/Service: Nursing Dept	Associate Investigator(s): Linda Yoder, RN, MBA PhD Sondra Perdue, BA MS PhD Anne Coscarelli, BA MA PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): As a disease primarily of the elderly, the number of patients with heart failure is ever-increasing with the "graying of America" and therapeutic advances to decrease mortality rates. In spite of increasingly sophisticated medical care, mortality rates are highest for the heart failure patient population.

Technical Approach: Research design/methods, and further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-129 Status: Ongoing

Cancer-Related Fatigue: An Exploratory Study

Start date: 1 Aug 95	Estimated completion date:
Principal Investigator: Linda Yoder, LTC, AN	Facility: BAMC
Department/Service: Nursing Dept	Associate Investigator(s): Lynne Connelly, RN PhD Lilly J. Noble, RN MSN Robert P. Savage, RN BSN Connie Johnson, Rn BSN Sandra J. Begley, RN BA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): Oncology healthcare providers and cancer patients agree that fatigue is highly prevalent among those being treated for cancer or recovering from a cancer illness. However, little is known about the fatigue experience from the perspective of the patient. This perspective is critical because fatigue is a subjective experience.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-131 Status: Ongoing

Outcomes Management: A Mechanism for Predicting Post-Operative Wound Infections

Start date: 17 Jul 95	Estimated completion date:
Principal Investigator: Julie Ann Blanke, AN	Facility: BAMC
Department/Service: Surgery/Cardiothoracic Surg Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): Nosocomial infections following open heart surgical procedures remain a potentially serious complication to this procedure. Beyond increasing human suffering, postoperative wound infections frequently result in an increased length of stay and a financial loss to the hospital. There are inaccuracies in current database systems. The purpose of this grant is to use steps commonly associated with outcomes management to: a) develop a computerized database that will be used to track wound infection in this patient population, b) define accurate wound infection rates for the cardiothoracic surgery service based on the site of the infection and c) identify patient characteristics that may increase the risk of surgical wound infection.

Technical Approach: A non-experimental, descriptive design is proposed to examine the risks of post-operative wound infections for open heart surgery patients. The sample will consist of all patients presenting to BAMC between 1 Jan 96 and 31 Aug 96 for cardiothoracic surgery. Inclusion criteria are: 18 years of age or older, undergoing open heart surgery, able to speak, read and write English, and able to give informed consent. Based on a power analysis, using a power of 0.80, a medium effect size (.30) and a 0.5 level of significance with five degrees of freedom, a sample size of 200 patients will be needed.

Progress: No report available as of this date. Annual review due Jul 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-82 Status: Ongoing

Title: Simulation of Cervical Diameter Measurements: An Appraisal of Accuracy

Start date: 14 May 93	Estimated completion date: 1 Jan 94
Principal Investigator: John Y. Phelps, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s): Michael H. Smyth, M.D. Kenneth Higby, M.D. Allan R. Mayer, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 123  
 Total number of subjects enrolled to date: 123  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): To assess the accuracy of clinical cervical diameter measurements using cervical simulators, and to compare these results among attending obstetricians, residents of various year levels, and labor and delivery nurses. Methods and results included in protocol.

Technical Approach: Specifics outlined in protocol.

Progress: Project completed and submitted for publication. We determined accuracy to be about 90% when allowed for an error of plus-minus 1 cm and no difference in accuracy between providers with different levels of experience.

# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: C-94-30                      Status: Ongoing

Title: Comparison of Anti-Hypertensive Agents for Hypertensive Emergencies in Pregnancy: A Pilot Study"

Start date: 14 Jan 94	Estimated completion date:
Principal Investigator: Kenneth Higby, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: Labetalol, clonidine, diazoxide, nifedipine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Since Apresoline is no longer being manufactured by Ciba-Geigy it is necessary to look at alternative forms of therapy for hypertensive emergencies in pregnancy. Desire to determine which agent (labetalol, clonidine, diazoxide, nifedipine) is most effective and has the least adverse effects upon patients. This has not been evaluated to date.

Technical Approach: Study design, study outcome monitors, sample size, subject population, etc. outlined in protocol.

Progress: We have not enrolled any protocols to date. There were some initial problems attaining the drugs as ward stock from the pharmacy but this is being resolved. Hopefully patients will be recruited soon.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-45 Status: Ongoing

Title: Timing the Postcoital Test: Use of a Home Urinary LH Test Versus Traditional Methods

Start date: 7 Feb 94	Estimated completion date:
Principal Investigator: Mark Marconi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: postcoital, BBT charts, home urinary LH test	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if use of a home urinary LH test improves the accuracy of timing the postcoital test, compared with traditional timing methods such as BBT charts & menstrual history.

Technical Approach: This study is designed to test whether home urinary LH determination improves the timing of postcoital testing, as compared with BBT charts and menstrual history. The patients to be studied will be infertile couples presenting to BAMC E&I clinic for initial infertility evaluation. Female subjects included will be between the ages of 18 & 40 with regular cycles with menses every 21-35 days and have ovulation confirmed by a d21 progesterone level >4 ng/ml. Exclusion criteria will include treatment with clomid or pergonal, lower genital tract infection, oligo- or azospermia, cervical anomalies, prior cervical surgery, & history of cervical factor infertility. The number of subjects required is 25. Further details in protocol.

Progress: Investigator did not provide a report. Status of study is unknown.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-50 Status: Ongoing

Title: The Effect of Subcutaneous Terbutaline Therapy on Glucose Tolerance in Pregnancy as Assessed by a Modified Bergman's Minimal Model

Start date: 7 Feb 94	Estimated completion date:
Principal Investigator: Craig E. McCoy, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: Terbutaline, pathophysiologic, terbutaline-induced	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To elucidate the pathophysiologic effects of terbutaline-induced changes in carbohydrate metabolism.

Technical Approach: Hypothesis is that subcutaneous Terbutaline has no significant effect on glucose metabolism.

Progress: Haven't gotten the patients to qualify as candidates. Plan to continue.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-63 Status: Completed

Title: Evaluation of the Safety and Effectiveness of HAL-C™ Coating Solution (Sodium Hyaluronate Solution in Surgery)

Start date: 11 Mar 94	Estimated completion date: 31 Dec 94
Principal Investigator: Dan Gehlbach, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: adjuvant, serosal, de novo, postsurgical, sodium hyaluronate, phosphate buffered saline, adhesions	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 362  
 Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): To evaluate the safety and effectiveness of HAL-C™ as a surgical adjuvant when used to coat serosal tissues thereby reducing the incidence, and/or severity, and/or extent of postsurgical de novo adhesions. Two different concentrations of HAL-C™, 0.2% and a 0.4% solution of sodium hyaluronate (w/w), will be compared to a control solution, phosphate buffered saline, referred to as PBS in this protocol.

Technical Approach: This multi-center study is designed as a three-way, randomized, double blind, safety and effectiveness study. Patients will be randomized to receive one of the following test solutions:

0.2% HAL-C™ - treatment

0.4% HAL-C™ - treatment

Phosphate buffered saline (PBS) - control

The study will be conducted at up to fifteen investigational sites. Multiple applications of the study solution will be made during each initial surgical procedure. Safety data will be evaluated from baseline through one month following the initial surgery. Effectiveness will be determined by comparing the incidence, severity, and extent of postsurgical adhesions present at baseline and at the time of a scheduled (second-look) surgery among the three groups. Further specifics ref inclusion/exclusion criteria, methodology, etc. given in protocol.

Progress: AUG 95: Dr. Gehlbach notified the IRB that the sponsor has completed enrollment of 362 patients for study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-92 Status: Ongoing

Title: Sterilization Regret in a Military Population

Start date: 11 Apr 94	Estimated completion date:
Principal Investigator: Stacey Thornton, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): Dan Gehlbach, M.D. Lauren Gehlbach, RN, MS, CNS
Key Words: sterilization, tubal ligation reversal	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 150  
Total number of subjects enrolled to date:  
Periodic review date: Apr of ea yr Review results:

Objective(s): Among women in a military population who seek reversal of tubal ligation, to determine what factors they identify as responsible for their desire to overturn a permanent procedure.

Technical Approach: A questionnaire will be administered to three groups of women (1) women currently seeking reversal of tubal ligation (approx 75), (2) women who have undergone tubal reanastomosis at BAMC in the past two years (approx 100), and (3) women of age 25-40 with a tubal ligation who are not interested in sterilization reversal (approx 100). Questionnaire will have 17 questions from five different categories: (1) Counseling - Physician Behavior, (2) Counseling - Patient Behavior, (3) Expectations, (4) influences, and (5) Economics. It will contain no patient identifiers and the patients will be counseled that their responses will not influence their medical care or chance for sterilization reversal. Further specifics and statistic input is outlined in protocol.

Progress: 4/95: Data collection still in progress.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-08 Status: Terminated

The Physiologic and Clinical Effects of Low Fat Diets in Pregnant Military Personnel

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Manuel Morales, M.D.	Facility: BAMC/Baylor School of Medicine
Department/Service: OB-Gyn	Associate Investigator(s): David L. Hachey, PhD, Peds/Baylor
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov of ea yr Review results: \_\_\_\_\_

Objective(s): To establish two populations of pregnant women who consume either a standard military diet (36% fat or a special low fat diet (25%). These study populations will be used to evaluate the effect of dietary fat intake during pregnancy on several indices of clinical outcome, metabolic responses, energy expenditure and body composition changes in active duty military personnel. In addition, the diets will be continued for 60mo postpartum to evaluate the effect of fat intake on the ability to meet physical conditioning requirements.

Technical Approach: Study design, population, methods, etc. outlined in protocol.

Progress: Nov 95: The grant for this study (thru Womens' Health Initiative) was not approved. No patients have ever been enrolled. (Dr. Higby)

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-47 Status: Ongoing

Influence of Parenteral Progesterone Administration on the Prevalence and Severity of Mastodynia in Active Duty Servicewomen

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Jeff Anderson, M.D.	Facility: BAMC, DACH, TAMC
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): A study questionnaire will be distributed to approximately 6% of active duty servicewomen in the US between the ages of 18 and 44 in a multi-institutional cross-sectional study comparing women receiving parenteral progesterones (medroxyprogesterone acetate or levonorgestrel) with a control group. The specific aims of this study are to: Assess the efficacy of progesterones in the prevention and treatment of mastodynia. Determine the prevalence and quantitate the severity of mastodynia among active duty servicewomen. Quantitate the impact of mastodynia on productivity and military readiness. Assess whether health care providers are meeting the expectations of women with mastodynia.

Technical Approach: Study design and specifics are outlined in protocol.

Progress:

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-132 Status: Ongoing

## Pertussis Immunity in an Obstetric Population

Start date: Sep 95	Estimated completion date:
Principal Investigator: Bradley K. Heim, M.D.	Facility: BAMC
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): Keneth Higby, M.D. Cynthia L. Eaton, M.D. Patrice Staten, M.D. Jerry Merrill, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of the study is to determine the immune status to Pertussis in a sample of 600 obstetrical patients between the ages of 18 and 45. Enzyme-linked immunosorbent assay (ELISA) techniques will be used to measure the presence or absence of serum IgG antibodies to purified pertussis toxin (PT).

Technical Approach: This is a prevalence study to report the immune status of an obstetric population. We will determine the presence or absence of IgG immunoglobulin antibodies using purified Bordetella pertussis toxin as the antigen in the sera of consecutive pregnant women presenting for care at BAMC and University Hospital. Anticipate the enrollment of approximately 600 patients.

Progress:

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-13 Status: Ongoing

Title: Islet Cell Hyperplasia of the Pancreas in Adults: An Immunohistochemical and Morphometric Study

Start date: 4 Dec 92	Estimated completion date: 4 Dec 94
Principal Investigator: Melton H. Fish, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology	Associate Investigator(s): M. H. Enghardt, M.D. J. I. Smith, M.D. K. J. Carlin, M.D. I. A. Chapa, MT E. Ayala, MA
Key Words: Islet cell hyperplasia, pancreas, nesidioblastosis, hyper insulinemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: N/A  
 Total number of subjects enrolled to date: N/A  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether or not the pancreatic endocrine volume - measured as area of endocrine tissue and expressed as a percentage of total glandular area - in two BAMC cases of patients with hyperinsulinemic hypoglycemia differs significantly from the relative endocrine volume in pancreata for age- and sex-matched controls. In contradistinction to the studies which disclaim an increase of endocrine volume, we hypothesize that one is present in our cases.

It is necessary to address a thorough review of the world's literature in order to completely document experience with diagnosis and with both medical and surgical therapy of hyperinsulinemic hypoglycemia caused by nesidioblastosis/islet cell hyperplasia. Modes of therapy and their outcome from all reported cases in adults, including our own, will be tabulated and evaluated.

Technical Approach: Archival tissue from two patients. Control tissues from age and sex matched control pancreata obtained via South Texas Organ Bank. Animal studies not required.

Progress: Awaiting set-up of color imaging system.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-116 Status: Ongoing

Title: Development of a Synthetic Biologic Control for Immunohistochemical Procedures

Start date: Aug 93	Estimated completion date:
Principal Investigator: Michael H. Enghardt, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology and Area Laboratories	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): Design and manufacture a semisynthetic tissue control using red cell membranes, latex granules and purified antigen.

Technical Approach: Pig blood will be used as the source of red cells. Blood may be collected from any pig that is on a terminal study and is a part of an approved animal use protocol. The blood will be collected while the animal is anesthetized, just prior to euthanasia. Further details in protocol.

Progress: Tests in progress in Dept of Clinical Investigation.  
 Aug 95: Patent application pending.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-85      Status: Ongoing

Organochlorine Exposure and Breast Cancer

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Thomas S. Mego, M.D.	Facility: BAMC
Department/Service: Pathology	Associate Investigator(s): Richard A. Cassidy, MAJ MS Dennis Kohler, SPC MS David W. Sees, CPT, MC Mary H. Wilson, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To measure organochlorine exposure by improved methodology in human breast lipids and blood serum, and determine if there is a relationship to an increased risk for infiltrating ductal carcinoma of the breast.

Technical Approach: The hypothesis to be tested is that environmental toxins, specifically the organochlorines oxychlordan, heptachlor epoxide and the DDT residue DDE (dichlorodiphenyl dichloroethane), are associated with infiltrating ductal carcinoma of the breast.

Progress: No report available as of this date. Annual review due Mar 96.

# Detail Summary Sheet

Date: 1 Dec 9 Protocol Number: C-95-144 Status: Ongoing

Surveillance of Antibiotic Resistance Among Invasive Strains of Streptococcus Pneumoniae in San Antonio

Start date: 28 Sep 95	Estimated completion date:
Principal Investigator: A. Christian Whelen, MAJ, MS	Facility: BAMC
Department/Service: Department of Pathology	Associate Investigator(s): James H. Jorgensen, PhD Jan Evans Patterson, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate CDC's current surveillance system for drug-resistant *Streptococcus pneumoniae* based on the epidemiology of invasive isolates identified at participating sentinel hospitals (most recently 13 hospitals in 12 states; 3). It is proposed to perform active population-based surveillance of invasive pneumococcal infections for a one year period and two period prevalence surveys of adult and pediatric respiratory pneumococcal isolates during the winter months in a large South Texas city to evaluate the sensitivity and representativeness of the current CDC system. This proposal has been prepared in response to and in accordance with CDC RFP No 200-94-0842 (P).

Technical Approach: Outlined in protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-79-87 Status: Ongoing

Title: Appetite and Pectin.

Start date: 9 Sep 87	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Appetite Obesity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50  
 Total number of subjects enrolled to date: 73  
 Periodic review date: Sep of ea yr Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.  
 Sep 95: Abstract written and accepted by American College of Nutrition.  
 Progress: Three adult patients were recruited. There was a problem in procuring pectin. When the pectin in appropriate form arrives, I will study the adult subjects. The permission to enroll adults was requested and granted by Clinical Investigation.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-62-90 Status: Ongoing

Title: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center).

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Terry Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Glenn Edwards, MAJ, MC, WRAMC David Maybee, COL, MC, WRAMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: May of ea yr Review results: Continue

Objective(s): 1) To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors.

2) To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

Technical Approach: To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 weeks, and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

Progress: Study still continuing. No reportable data as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-2 Status: Ongoing

Title: Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor

Start date: Feb 92	Estimated completion date:
Principal Investigator: COL Chandra Tiwary, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Childhood Obesity Incidence, Duty Status	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1500  
 \_Total number of subjects enrolled to date: 2000  
 \_Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To describe the incidence density of childhood obesity among the dependents of US Army personnel. The association between incidence of obesity and the active duty or retiree status of the sponsor will also be assessed.

Technical Approach: All children beyond the age of 1 year attending the pediatric and adolescent clinic of the Brooke Army Medical Center will be included in this study. Their order of birth, name, gender, date of birth/age, height, weight, the sponsor's social security number, rank, duty status (active duty or retired), year when retired from the military, age on retirement and the current age will be recorded.

Progress: Approximately 1500 children who attended this pediatric clinic had their forms filled out. About 470 charts have been entered in the database in a computer, we will analyze the data when all the forms have been entered in database. We still need a data entry person for about two weeks time.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-09 Status: Ongoing

Title: Extracellular Fluid Volume Loading and Prevention of Amphotericin B Nephrotoxicity

Start date: 19 Oct 92	Estimated completion date:
Principal Investigator: Luisa Gomez, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): John Roscelli, M.D. Theodore Cieslak, M.D. Martin Weise, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
 Total number of subjects enrolled to date: 19  
 Periodic review date: Oct of ea yr Review results:

Objective(s): To study the effects of acute extravascular fluid volume expansion at the time at the time of Amphotericin B administration on the prevention of Amphotericin B induced nephrotoxicity in patients less than 23 years of age. The study will be randomized, nonblinded and prospective.

Technical Approach: All pediatric patients <23 years of age who require Amphotericin B for suspected or proven deep mycosis will be eligible for the study. Patients excluded from the study will include those with known cardiac disease and those with significant renal disease - specifically a creatinine clearance of <50 ml/min per 1.73 m<sup>2</sup>. Calculated sample size for statistical significance is based on having an 80% chance of detecting an 80% reduction in the previously described 80% incidence of azotemia in the control group. This will require a sample size of 20 patients including 10 patients in the control group and 10 patients in the study group.

Progress: 94: Patient accrual and data collection still in process.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-61 Status: Ongoing

Title: Low-Volume vs High-Volume Blood Culture Sampling in Immunocompromised Children

Start date: 23 Dec 92	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): It has previously been suggested that low-volume blood culture sampling is adequate to detect most cases of bacteremia in children. Recent studies, however, demonstrate that large proportion of sepsis in immunocompromised children involves low microbial colony counts. This study will prospectively seek to determine whether high-volume blood sampling for culture will significantly improve the ability to detect bacteremia in this group of children.

Technical Approach: Specifics outlined in protocol.

Progress: The principal investigator has been deployed to Panama. The exact status of this protocol is unknown.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-121 Status: Completed

Title: Exogenous Surfactant Therapy in Premature Infants: A Multicenter Trial

Start date: 21 Jun 93	Estimated completion date:
Principal Investigator: Howard S. Heiman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Deborah J. Leander, R.N. Joanna C. Beachy Barbara S. Turner William Dean Glover
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): The leading cause of death for prematurely born infants born in the US is Respiratory Distress Syndrome (RDS). Specific aims of this study are to incorporate findings from the current study and extend knowledge on exogenous surfactant types of exogenous surfactant (Exosurf & Survanta), three methods of administration (Sideport adapter, feeding tube, and double lumen endotracheal tube) and the resulting neonatal physiologic responses and outcomes. Secondary aim will be to determine the relationships between type of surfactant and administration technique, nursing assessed neonatal clinical cues of a hemodynamically significant patent ductus arteriosus, and neonatal outcomes.

Technical Approach: Hypothesis, synopsis, nursing/medical applications, status, study plan, and specifics outlined in protocol.

Progress: The patients have tolerated the study procedures well. There have been no complications. They have responded positively to the surfactant given by the different methods. The results are under analysis at Madigan Army Medical Center. We have requested an extension on the use of FY 94 funds through March of 1995.

Jun95: No problems encountered by the ten patients. Study is completed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-03 Status: Terminated

Title: Growth and Endocrine Function in Children After Bone Marrow Transplantation

Start date: 19 Oct 93	Estimated completion date:
Principal Investigator: David A. Nickels, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Terry Pick, M.D. Allen Potter, M.D.
Key Words: pubertal development, endocrine function, BMT	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16  
Total number of subjects enrolled to date: 16  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To prospectively study the effect of BMT on growth, pubertal development, and endocrine function in children undergoing BMT at BAMC.

Technical Approach: Study design; data collection/methods; statistical analysis and specifics are included in protocol.

Progress: Sixteen patients have been enrolled in the protocol in the first year to date. Patients are to be reassessed every six months as to their growth and endocrine function, so very little follow-up data has been collected at this point, and no statistical analysis is possible at this time. Patients will continue to be enrolled and follow-up studies will be obtained as detailed in the protocol. One problem to be overcome is that many of the patients come to BAMC from a great distance for their BMT procedure and then receive their ongoing follow-up care at another medical center closer to where they live. We are attempting to coordinate with the distant sites to obtain the patient's studies locally if they are not returning to BAMC at regular intervals.

Sep 95: PI PCSd - study terminated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-06 Status: Ongoing

Title: Immunologic Characterization of Coagulase-Negative Staphylococci

Start date: 14 Sep 94	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Stephen M. Dentler, M.D. Michael A. Battista, M.D. Howard S. Heiman, M.D. Gerald W. Fischer, M.D.
Key Words: Staphylococci, virulence, commensal strains, serotype	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50 - 80 (100 samples)

Total number of subjects enrolled to date:

Periodic review date: Sep ea yr Review results:

Objective(s): To assess the role of coagulase-negative staphylococcal serotype-specificity with respect to virulence. We hypothesize that only serotype II CNS strains are true human pathogens, while commensal strains may be of any serotype. We propose to demonstrate this by comparing commensal and pathogenic strains by means of a simple test of proportions.

Technical Approach: Medical applications, status, proposal, methods including statistical analysis and further details are outlined in protocol.

Progress: Sep 95: Finished collecting clinical specimens; starting bench phase of research.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-17 Status: Ongoing

Title: Electrocardiographic Voltage Criteria Are Too Sensitive for Left Ventricular Hypertrophy in Children

Start date: 13 Dec 93	Estimated completion date:
Principal Investigator: Patrick Glasow, M.D.	Facility: Ft Sill & Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: left ventricular hypertrophy (LVH)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22  
 Total number of subjects enrolled to date: 22  
 Periodic review date: Review results:

Objective(s): To assess the clinical effectiveness of electrocardiographic (EKG) voltage criteria for detecting left ventricular hypertrophy (LVH), and test efficacy of repeating EKGs prior to proceeding to more expensive tests.

Technical Approach: Subject population will be all pediatric patients (age birth - 23, male and female) referred to BAMC pediatric cardiology for possible LVH on EKG (except those with left bundle branch block previously known structural congenital heart disease). The study size will be approximately 100 patients.

Progress: Original PI Michael Serwacki, M.D., is continuing study at Fort Sill and Dr. Glasow is assuming study at BAMC. Significant findings indicate study should be continued.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-67 Status: Ongoing

Title: Multicenter Double-Blind, Study of Fluconazole in the Early Empirical Treatment of Suspected Fungal Infections in Febrile Neutropenic Patients Undergoing therapy for Cancer

Start date: 22 Mar 94	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: Fluconazole, empirical, fungemia, febrile, neutropenic, granulocytopenia, visceral	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the efficacy and safety of early systemic empiric therapy with fluconazole for the treatment of suspected fungal infections complicating granulocytopenia. (Suspected Fungal Infection is defined as new fever with neutropenia. Proven Fungal Infection is defined as culture and/or biopsy documented invasive fungal infection, esophageal candidiasis, fungemia, or deep visceral fungal infection [e.g., hepatosplenic candidiasis]. To determine if fluconazole decreases the need for administration of amphotericin B [including both empiric and therapeutic use]. To determine the influence of fluconazole on patterns of fungal colonization and acquisition during the neutropenic period. To determine the effect of fluconazole on endogenous and acquired fungal flora as measured by the in vitro susceptibility of colonizing and infecting fungi before, during and after administration of fluconazole. Following their episode of granulocytopenia, study patients will be followed for 14 days to determine if early Fluconazole empiric therapy has an effect on survival of cancer patients with fever and neutropenia.

Technical Approach: Study design, patient selection, management of study medication and other specifics are outlined in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-101 Status: Ongoing

Title: Effect of Exercise on Blood Glucose Level Among Children with Insulin Dependent Diabetes Mellitus (IDDM)

Start date: 31 May 94	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: diabetes mellitus, plasma, ketones	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: May of ea yr Review results:

Objective(s): To define the effect of exercise on the blood sugar level of the child with IDDM. To find the effect of exercise on plasma and urinary ketones in children with IDDM.

Technical Approach: The effect exercise has on the blood glucose level in a child with IDDM may, once defined, be used to prescribe a regular program of physical fitness for the child with IDDM. This knowledge may also be utilized to treat the diabetic child who develops mild hyperglycemia with decreased insulin than might otherwise be required.

Progress: Five children and adolescents with diabetes have been enrolled in the study. The laboratory values are not available in all children. The results have not been analyzed, it appears that in some children the blood glucose falls after the exercise.

5/95: No more patients have been enrolled, but more are planned.

Analysis of results:

The blood glucose remains stable or falls after exercise (during treadmill exercise but at home the blood sugar falls consistently after exercise (could be due to less stress at home).

The plasma ketone vary after exercise.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-124 Status: Ongoing

Title: Epidemiologic Study of Cystic Fibrosis (ESCF)

Start date:	Estimated completion date:
Principal Investigator: Stephen C. Inscore, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): H. Joel Schmidt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
 Total number of subjects enrolled to date: 20  
 Periodic review date: Review results:

Objective(s): To longitudinally characterize the variability in and monitor the decline of pulmonary function in CF patients and relate these characteristics to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. To longitudinally characterize the rate of pulmonary exacerbations requiring specific antibiotic therapy in CF patients and relate these exacerbations to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. To collect information on the safety of long-term treatment with Pulmozyme (dornase alfa) and to examine trends in pulmonary function and rates of pulmonary exacerbations that relate to the effectiveness of long-term treatment with Pulmozyme.

Technical Approach: Patient criteria, study design, evaluations, statistical analysis and further specifics are outlined in protocol.

Progress: Too early for preliminary conclusions. Initial results will be reported this fall at National LCF Conference in Orlando, FL, as a part of the National Data Collection for the ESCF study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-140 Status: Completed

Title: A Six Month Randomized, Parallel Group, Double-Blind Clinical Trial Comparing Amiloride Hydrochloride with Placebo in Adolescent and Adults with Cystic Fibrosis

Start date: 29 Aug 94	Estimated completion date:
Principal Investigator: Stephen C. Inscore, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of nebulized amiloride hydrochloride 4.5 mg (4.5 ml of 1 mg/ml, QID) with placebo in the treatment of adult and adolescent patients with mild to moderate cystic fibrosis. The primary efficacy assessment will be the decline in pulmonary function over the duration of the trial. To compare the quality of life as assessed by the Quality of Well-Being Scale and the MOS Short-form 36 of amiloride-treated vs placebo-treated adult and adolescent patients with mild to moderate cystic fibrosis. To compare the safety profile of nebulized amiloride hydrochloride 4.5 mg (4.5 ml of 1 mg/ml, QID) with placebo in the treatment of adult and adolescent patients with mild to moderate cystic fibrosis. Safety assessments will include clinical laboratory tests and collection of adverse events.

Technical Approach: Study procedures, data procurement/analysis, clinical supplies, investigator's obligations and specifics are outlined in protocol.

Progress: This is a new study. There is no reportable data.  
 Jul 95: Closed



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-43 Status: Ongoing

Impact of Endotracheal Suctioning with Zero End Expiratory Pressure (ZEEP) versus Positive End expiratory Pressure (PEEP) on Physiology of Premies

Start date: 20 Mar 95	Estimated completion date:
Principal Investigator: Christine Sanford, AN	Facility: BAMC
Department/Service: Pediatrics	Associate Investigator(s): Patrice Chandler, AN Howard S. Heiman, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): Specific aims of this study are: 1. Is there a difference in oxygenation intracranial pressure, heart rate, transcutaneous carbon dioxide tension, mean airway pressure and blood pressure when premature infants receive endotracheal suctioning using positive end-expiratory pressure versus zero end-expiratory pressure? 2. Is there a difference in the amount of secretions recovered after 3 ETS procedures with PEEP versus 3 ETS procedures with ZEEP in premature infants?

Technical Approach: Data analysis, subjects, inclusion criteria and specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Mar 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-91 Status: Ongoing

## Effect of Storage Method on Urine pH Over Time

Start date: 6 Feb 95	Estimated completion date:
Principal Investigator: Stephen George, M.D.	Facility: BAMC
Department/Service: Pediatrics	Associate Investigator(s): John Roscelli, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): Clean catch urine samples obtained from cooperative Pediatric Ward patients and Pediatric Department Staff and House Staff will be collected. The pH of specimens stored by several different methods will be measured over set time intervals. Variations in pH by method of storage will be compared to determine if significant differences exist and if so which method best preserves pH.

Technical Approach: When evaluating Acid-Base disturbances, and particularly when assessing renal tubular acidosis accurate determination of urine pH is critical for diagnostic and therapeutic reasons. Since immediate measurement of fresh urine is not always achievable, reliable storage methods for preserving urine pH are needed. Further specifics are in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-94      Status: Terminated

Dietary Protein Needs and Protein and Amino Acid Metabolism of Military Women and Men

Start date: 19 Jun 95	Estimated completion date:
Principal Investigator: Kathleen J. Motil, M.D.	Facility: BAMC
Department/Service: Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To examine the adaptive responses of body protein and amino acid metabolism in military women to reduced protein intakes as a means to assess dietary protein needs, and to determine the extent to which the military woman's body composition and physical performance influence the magnitude of her protein needs.

Technical Approach: (1) Dietary protein requirements are higher in military than in civilian women because of the differences in body composition and physical performance between these two groups, (2) dietary protein requirements will be similar between military women and men after accounting for differences in their body composition and physical performance in the occupational and field setting, and (3) dietary protein requirements of military women and men are equally higher in the field than in the occupational setting.

Progress: Study terminated because lack of funding. Should funding status of this protocol change, reinstatement will be requested.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-98      Status: Ongoing

The Prevalence of Premature Sexual Development in Children Attending the Pediatric Clinics

Start date: 10 Jul 95	Estimated completion date:
Principal Investigator: Chandra Tiwary, M.D.	Facility: BAMC
Department/Service: Pediatrics	Associate Investigator(s): James D. Odom, CPNP COL AN Nick Geralde, CPT MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine a) the prevalence of secondary sexual character development among children aged ten years or less who use hormone containing hair preparation (b) If the prevalence of premature sexual development between two groups of children, those who use hormone/placenta containing hair preparation and those who do not use such products, is different.

Technical Approach: Medical application, status, plan and specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Jul 96.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-135      Status: Ongoing

A Phase III Placebo Controlled Clinical Trial (PC-TNDS-002) to Study the Efficacy of Tobramycin for Inhalation in Patients with Cystic Fibrosis (CF)

Start date: 11 Sep 95	Estimated completion date:
Principal Investigator: Stephen C. Inscore, M.D.	Facility: WHMC/BAMC
Department/Service: Pediatrics	Associate Investigator(s): H. Joel Schmidt, M.D. Jan Westerman, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): This study is a multi-center, double blind, placebo controlled randomized trial. Patients will receive either aerosolized tobramycin 300 mg twice daily or placebo for 28 days followed by 28 days off study drug. This treatment cycle will be repeated twice for a total of three cycles. the projected completion date is 10 months after the initial patient is enrolled. The overall objectives of this project are to establish the safety and efficacy of twice daily administration of 300 mg tobramycin for inhalation given as repeated, intermittent, short term (28 days) therapy for 168 days in patients with cystic fibrosis who are colonized with *Pseudomonas aeruginosa*. Primary and secondary objectives are further delineated on page 15 of the accompanying PathoGenesis Corporation Protocol PC-TNDS-002.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-12-77 Status: Ongoing

Title: Intravenous Administration of I<sup>131</sup> (NP59) for Adrenal Evaluation of Imaging.

Start date: 15 Nov 76	Estimated completion date:
Principal Investigator: Gilbert Sostre, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words: Adrenal Scan	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 11  
 Periodic review date: Nov of ea yr Review results: Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1 mCi in adults and 15 Ci/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: There have been no new patients enrolled since 16 September 1992. Study remains open for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-47-89 Status: Ongoing

Title: Evaluation of <sup>131</sup>I-miBG (<sup>131</sup>I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia.

Start date: 20 Mar 89	Estimated completion date:
Principal Investigator: James D. Heironimus, LTC, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6

Total number of subjects enrolled to date: 40

Periodic review date: Mar of ea yr Review results: Continue

Objective(s): To evaluate the use of <sup>131</sup>I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by <sup>131</sup>I-miBG scintigraphy.

Progress: The principal investigator has PCS'd from BAMC as has the associate investigator. The exact status of this study is unknown.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-108-89 Status: Terminate

Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium Antimony Trisulfide Colloid (99m Tc-Sb<sub>2</sub>S<sub>3</sub> for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy ..

Start date: 8 Sep 89	Estimated completion date:
Principal Investigator: James D. Heironimus, Lt COL, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Radiology	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 9  
 Periodic review date: Sep of ea yr Review results: Terminate

Objective(s): To determine the effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. For evaluation for lymphedema, intradermal injections of the radiopharmaceutical will be made in the distal extremities of interest. To evaluate the lymph drainage paths of a dermal region, injections will be made intradermally immediately adjacent to the site of the skin lesion/biopsy site. For all studies, scintigraphic imaging will be performed using an Anger Gamma Camera system. Multiple use of the appropriate areas will be attained immediately following the injection of the radiopharmaceutical as well as approximately 1-4 hours after injection. Body outlining and/or flood field imaging techniques will be performed to provide additional positional information.

Progress: Principal Investigator has PCSd and no one else as assumed study; therefore terminate study.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-85 Status: Completed

Title: Efficacy of the Lateral Chest Radiograph on Computed Radiography Systems

Start date: Jul 93	Estimated completion date: Jul 94
Principal Investigator: Timothy J. Cramer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology	Associate Investigator(s): Anna K. Chacko, M.D. Joseph P. Spirnak, M.D. Raoul O. Hagen, M.D. Al Gest, M.D. James M. Lamiell, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: Completed

Objective(s): To assess the efficacy of the lateral chest radiograph on routine outpatients using computed radiography systems.

Technical Approach: This is a prospective study of 3000 PA and Lateral chest radiographs obtained on the CR system. Patients will be from the Emergency Dept and Acute Care Clinic. No patients will be excluded.

Progress: We encountered difficulty with films. The study has been restarted and is currently in progress.

May/95: Completed, awaiting input.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-47 Status: Ongoing

Title: A Prospective Evaluation of Technetium 99<sup>m</sup> Sestamibi in The Detection of Breast Cancer

Start date: 1 Jan 94	Estimated completion date: 31 Dec 94
Principal Investigator: Gilberto Sostre, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology/Nuc Med Svc	Associate Investigator(s): Rashmikan Shah, M.D. Neil Katz, M.D.
Key Words: Technetium 99 <sup>m</sup> , Sestamibi, validate, establish, sensitivity, specificity	John Thomas, BCNP Vimal Sodhi, M.D. Johnny D. Alvarez, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): The use of Tc<sup>99m</sup> Sestamibi in this study would attempt to validate and establish the sensitivity and specificity of Tc<sup>99m</sup> Sestamibi in detecting breast cancers. This technique would be based on the increased biological differential uptake of breast cancer cells compared to normal breast cells.

Technical Approach: It is planned to carry out this open design study in two phases comparing Tc<sup>99m</sup> Sestamibi uptake in patients who are initially referred for a breast lump to mammography utilizing the abnormal breast biopsy as the gold standard for malignancy. If Tc<sup>99m</sup>Sestamibi's specificity and sensitivity are proven in discrete, palpable lesions for breast carcinoma malignancy, the second phase would add Tc<sup>99m</sup>Sestamibi scintigraphy to patients undergoing mammography who are found to have diffuse, fibrocystic breast disease or questionable mammograms without palpable lesions who are referred for a diagnostic breast biopsy.

Progress: Awaiting funding approval from the Jackson Foundation before starting study. Anticipate enrolling patients in mid January 1995.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-44 Status: Ongoing

A Randomized, Double-Blind, Placebo Controlled Study of the Effect of Cilostazol on Gastric Emptying in Patients with Intermittent Claudication Secondary to Peripheral Vascular Disease

Start date: 19 Dec 94	Estimated completion date:
Principal Investigator: Gilberto Sostre, M.D.	Facility: BAMC
Department/Service: Nuclear Medicine	Associate Investigator(s): Scott Williams, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 17  
Total number of subjects enrolled to date: 17  
Periodic review date: Dec of ea yr Review results: Ongoing

Objective(s): To evaluate the effect of oral cilostazol on gastric emptying in patients with intermittent claudication secondary to peripheral vascular disease. The radionuclide gastric emptying of a standard meal will be performed as a baseline in these patients at entry into the study. On a separate day, the patients will undergo repeat gastric emptying study while on the oral cilostazol for at least 2 weeks. These studies will be compared to the baseline study to determine the effect of cilostazol on the gastric emptying. Further specifics in protocol.

Technical Approach: Exclusion data and specifics on diet are outlined in protocol.

Progress: Dec 95: No adverse effects. Need three more subjects; anticipate completion next month or two.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-89 Status: Ongoing

Ureteral Jets in Normal Pregnancy

Start date: 30 Jan 95	Estimated completion date:
Principal Investigator: Timothy Washowich, M.D.	Facility: BAMC
Department/Service: Radiology Dept	Associate Investigator(s): Brian Burke, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the character of ureteral jets as documented by color Doppler US in normal pregnant women.

Technical Approach: Description of subjects and controls, experimental design and methods, data collection, interpretation and statistical analysis are outlined in protocol.

Progress: No report available as of this date. Annual review due Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-79-88 Status: Ongoing

Title: Collaborative Ocular Melanoma Study.

Start date: 8 Sep 88	Estimated completion date: 1998
Principal Investigator: Clifford S. Slade, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): William L. White, MAJ, MC
Key Words: Melanoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: Sep of ea yr Review results: Continue

Objective(s): 1) To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: Unchanged. Collaborative Ocular Melanoma Study is designed to determine the most effective way to treat choroidal melanomas. Patients are divided into small tumors, medium tumors and large tumors based on diameter and thickness of the melanoma. Individuals in the small category are observed while individuals in the medium category are randomly divided into two treatment groups. One group was enucleated and the second will have radiation plaque therapy applied to the melanoma. Individuals in the large melanoma group are divided into either enucleation with preoperative radiation or enucleation without preoperative radiation.

Progress: One patient currently remains on study. Study is ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-115-89 Status: Completed

Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial.

Start date: 8 Sep 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
Key Words:	
Accumulative MEDCASE Cost:	Estimated Accumulative OMA Cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 4  
Periodic review date: Sep of ea yr Review results: Completion

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate and qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: There has been no change. The protocol remains open.  
Aug 95: No further patient entries. Request closure.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-61-90 Status: Terminated

Title: Swimming and Myringotomy Tubes.

Start date: 12 May 90	Estimated completion date:
Principal Investigator: Kweon I. Stambaugh, LTC, MC	Facility: Brooke Army Medical Center
Department/Service: Department Surgery/Otorhinolaryngology	Associate Investigator(s): Jeffrey Braaten, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 100  
 Total number of subjects enrolled to date: 160  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of ear infection while swimming with middle ear ventilation tubes.

Technical Approach: All patients undergoing myringotomy and insertion of ventilation tubes that are intact and patent during the swimming season, June thru September, will be included in the study. Swimmers and non-swimmers will be randomized by a table of random numbers. A variety of ventilation tubes will be placed based on the surgeons personal preference. Patients will be seen routinely two weeks postoperatively and then every three months thereafter until the tubes are extruded. Patients will be given a calendar and questionnaire. The days swimming, the number of ear infections, and their relationship to an upper respiratory infection will be recorded.

Progress: Both the Principal and Associate Investigators have PCS'd from BAMC. This study is on hold pending assignment of a new investigator.  
 Aug 95: Terminated per instructions of LTC S. Ramirez, MC, C, Oto Svc.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-91-90 Status: Completed

Title: The Incidence of Prostatism in Older Males Presenting for Herniorrhaphy.

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Kevin Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words: Prostatism Urine flow Rate	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 78  
Total number of subjects enrolled to date: 78  
Periodic review date: Aug of ea yr Review results: Completed

Objective(s): To determine the incidence of prostatism in males 40 years of age and older who present for herniorrhaphy.

Technical Approach: One hundred consecutive men scheduled for herniorrhaphy will undergo urodynamics evaluation in an attempt to detect asymptomatic or minimally symptomatic physiologically-significant bladder outlet obstruction secondary to prostatic hyperplasia. Should such obstruction be encountered, Urology consultation would be requested before herniorrhaphy is undertaken.  
Aug 95: Principal Investigator PCSd. Study closed.  
Progress: Study has been completed. Data collection in process.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-90 Status: Completed

Title: Effect of the Use of Perioperative Antibiotics in the Incidence of Wound Infection Following Mastectomy.

Start date: 1 Aug 89	Estimated completion date:
Principal Investigator: Steven B. Olsen, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Vascular Surg	Associate Investigator(s): Daniel P. Otchy, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 31  
 Total number of subjects enrolled to date: 38  
 Periodic review date: \_\_\_\_\_ Review results: Completed

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: This subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups: the first group will received intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotic would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: Study completed. Principal Investigator PCSd from BAMC.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-98-90 Status: Completed

Title: An Open Label Extension Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension.

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Thomas A. Rozanski, M.D.C
Key Words:	Douglas A. Schow, MAJ, MC
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 6  
Periodic review date: Sep of ea yr Review results: Completed

Objective(s): 1) To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia (BPH).  
2) To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.

Technical Approach: Patients who successfully complete the 16 week (double blind study may enter the open label extension study. They must do so within one week. Patients who withdrew from the 16 week study, after randomization, due to adverse experiences or lack of efficacy may also enter. The study is designated as an open-label, long-term, follow-up trial to the initial 16 week study. All patients in the open label trial will initially receive 1 mg of doxazosin daily and will be titrated upward at two week intervals, one dose level at a time, to a daily dose of 2, 4, 8, or 12 mg. A patient's upward titration will be dependent upon their adverse experiences, blood pressure response and BPH symptomatology. Once an optimal dose is achieved, it will be maintained unless the investigator determines that an adjustment in dose (lower or higher) is medically indicated.

Progress: During the past year, the same four patients remain on the study, all experiencing benefits of this agent. Patients with acceptable blood pressure and urinary symptoms with this agent will be kept at the dose achieved and periodically re-evaluated for patient satisfaction and blood pressure control. Enrollment closed. Ongoing for patient followup purposes.  
Aug 95: All patients with acceptable blood pressure and urinary symptom improvement with this agent will be kept at the dose achieved and periodically re-evaluated for patient satisfaction and blood pressure control. Study completed 29 Aug 95.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-50-91 Status: Ongoing

Title: Comparison of Trigger Point Injections Using Kerolac Tromethamine versus Saline in the Treatment of Myofacial Pain Syndrome.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Roger L. Wesley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): William Strong, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6

Total number of subjects enrolled to date: 6

Periodic review date: May of ea yr Review results:

Objective(s): To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

Technical Approach: Fifty adult volunteers who are referred to the pain clinic with myofascial pain syndrome will be enrolled in the double blinded, randomized study. Pain intensity and quality will be assessed using pressure algometry all visual analog pain scales. Patients will then be given trigger point injection with either ketorolac tromethamine or saline in a double blinded fashion. Pain reassessment will be done at 10 minutes, 6 hours, 1 day and 1 week following injection.

Progress: Principal investigator has separated from the Army. Currently there is no principal investigator to pursue this study. Data analysis is in progress.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-56-91 Status: Completed

Title: Urine Flow Rate Pre- and Post-Penile Prosthesis Implantation.

Start date: 4 Jun 91	Estimated completion date: 6/95
Principal Investigator: Kevin C. Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): MAJ (P) Samuel Peretsman, M.D.
Key Words: Urine Flow Rate Penile Prosthesis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50

Total number of subjects enrolled to date: 50

Periodic review date: Jun of ea yr Review results:

Objective(s): To determine 1) those patients with bladder outlet obstruction secondary to benign prostatic hypertrophy prior to penile prosthesis implantation and 2) the incidence and degree of decreased urine flow rate secondary to penile prosthesis induced urethral obstruction.

Technical Approach: All patients scheduled for penile prosthesis implantation will complete a questionnaire and undergo pre- and postoperative urine flow rate utilizing the Dantec Uroflowmeter<sup>®</sup>.

Progress: Ongoing. Thus far, no significant difference in the urine flow rate has been observed following penile prosthesis.

May 95: Implantation of a Duraphase Penile Prosthesis does not significantly alter one's urine peak flow rate. Dr. Shandera has PCSd to TAMC.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-73-91 Status: Ongoing

Title: Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias? A Double Blind, Randomized, Placebo Controlled Clinical Trial.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Janet Hays, MAJ, MC Greg Bowman, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Aug of ea yr Review results:

Objective(s): 1) To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentrations.

2) To determine the correlation of myocardial and MBC Mg concentrations with post-CPB arrhythmias (ventricular and supraventricular).

3) To determine if MgSO<sub>4</sub> administration (30 mg/kg followed by 15 mg/kg/hour x 4 hours) is efficacious in reducing the incidence of post-CPB arrhythmias.

4) To determine the correlation of right atrial and left ventricular myocardial Mg concentration.

Technical Approach: Patients will be randomized to receive either 30 mg/kg MgSO<sub>4</sub> or placebo (normal saline) during CPB followed by 15 mg/kg/hour or placebo for four hours. The right atrial appendage (200 mg) will be sampled for intracellular Mg concentration. A left ventricular myocardial sample (200 mg) will be obtained if the left ventricle is to be incised for valve repair or aneurysmectomy. Myocardial samples will be obtained prior to the administration of the study medication. The detection method for arrhythmias will be a continuous Holter monitoring (leads CM5 and II) both pre- and

C-73-91 (continued)

post-CPB.

Progress: We are still awaiting laboratory support for the magnesium levels from Department of Clinical Investigation.

Aug95: On hold due to time constraints.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-74-91 Status: Ongoing

Neoadjuvant Hormonal Therapy Prior to Radical Prostatectomy for Clinical Stage A and B Carcinoma of the Prostate (RENAMED) Randomized Prospective Study Comparing Radical Prostatectomy Alone versus Radical Prostatectomy Preceded by Androgen Blockade in Clinical B2 Prostate Cancer

Start date: 26 Oct 92	Estimated completion date:
Principal Investigator: LTC Ian Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Thomas a. Rozanski, M.D. John Foley, M.D. Douglas A. Schow, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 8 - 5 currently being followed  
Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of a combination of Lupron Depot 7.5 mg (leuprolide acetate for depot suspension) and Eulexin (flutamide) prior to radical prostatectomy in clinical stage B2 prostatic cancer as compared to no therapy before radical prostatectomy.

Technical Approach: Eight patients with clinical stage B2 carcinoma of the prostate were randomized to receive either radical prostatectomy or adjuvant hormonal therapy. Patients eligible for the study must have had no evidence of extraprostatic disease.

Progress: Study enrollment is complete. The patients remaining on study are seen every 6 months and monitored for disease progression or recurrence. During this reporting period, 2 patients were dropped from the study for disease progression. Neither received Lupron and Eulexin during the enrollment phase of the study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-76-91 Status: Ongoing

Title: Efficacy of Steroid in Reducing Post-Tonsillectomy Morbidity.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: James Lee, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): Sylvester G. Ramirez, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
Total number of subjects enrolled to date: 65  
Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, 2) by reducing postoperative swelling, and/or 3) allowing improved oral intake.

Technical Approach: The study group will include approximately 50 study subject and 50 controls. This study will compare post-tonsillectomy 1) pain, 2) tolerance of diet, i.e., liquids vs soft vs regular, 3) swelling, 4) temperature 5) weight fluctuation and 6) complications between patients receiving dexamethasone or placebo perioperatively.

Progress: Sixty-five patients have been entered but 100 is required for data analysis. Study is ongoing for patient accrual and data analysis.  
Aug 95: Still on-going.



# Detail Summary Sheet

Date: 1 Dec 95                      Protocol Number: C-90-91                      Status: Ongoing

Title: Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Urology/Surgery	Associate Investigator(s): Peter Ravdin, MC Edward J. Mueller, LTC, MC Eric J. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 4  
Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): 1) To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer.

2) To determine if immunization against LHRH will cause suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels in these patients.

3) To observe patients for signs of adverse effects following immunization.

Technical Approach: Four patients from BAMC will be referred on the study. The LHRH vaccine will be administered by Dr. Ravdin at the University of Texas Health Science Center on three occasions at two week intervals. Patients will return to BAMC for follow-up at monthly intervals for the first six months and then every three months for up to two years.

# Detail Summary Sheet

Date: 1 Oct 95 Protocol Number: C-91-92 Status: Ongoing

Title: Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Frank M. Robertson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To prospectively analyze a group of variables to include age, size of primary tumor, receptor status, presence of adenopathy on axillary ultrasound, ploidy status and percent s-phase in breast cancer patients with clinically negative axilla.

Technical Approach: Data to include age, primary tumor size, estrogen receptor status, progesterone receptor status, axillary ultrasound, ploidy status, s-phase fraction, and final anatomic pathology results will be collected on all patients treated for breast cancer at BAMC for a period of 18 to 24 months. In patients with suggestive physical exams or mammograms, the ultrasound will be obtained prior to any surgical intervention such as biopsy.

Progress: Dr. Robertson has left and the protocol is on hold. No one on this service is currently involved in this project.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-26 Status: Ongoing

Title: Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): 1) To determine the ED<sub>95</sub> of vecuronium bromide for train-of-four twitch height depression in the nonthermally injured patient. 2) To compare the ED<sub>95</sub> determined for these patients to that determined for thermally injured patients.

Technical Approach: Patients will be premedicated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium or ketamine as indicated by the patient's condition.

Progress: There has been no progress in obtaining patients to complete the study.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-92-27

Status: Ongoing  
(Reopened Jun 95)

Title: Analysis of Foot Surface Stress in Parachute Landing Falls

Start date: Reopened 28 Jun 95

Estimated completion date:

Principal Investigator:  
MAJ James P. Stannard

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Surgery/Orthopedic Surg Svc

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To analyze foot surface stress in PLF-s under varying conditions (footgear, terrain, velocity) utilizing an in-shoe foot force analysis system. This data will be used to: 1) understand the mechanics of high impact landig; 2) design and test equipment to protect paratroopers during airborne missions; and 3) recommend changes in training regimens and landing techniques.

Technical Approach: All jumps will be performed from a platform or a horizontal "slide" by US Army paratroopers on active jump status. An F-scan force analysis system will be used to measure landing forces during all jumps. System consists of an in-shoe transducer that is made up of 960 element matrix of 5mm square sensors linked to a 386 computer.

Progress: PI has returned from Womack Army Cmmunity Hospital and desires to resume study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-35 Status: Ongoing

Title: Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures

Start date: 25 Feb 92	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC CPT Brian Allgood, MC COL Allan Bucknell, MC
Key Words: DVT, Foot Pump Total Joint Arthroplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 75  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for deep venous thrombosis associated with hip fractures in individuals greater than 40.

Technical Approach: All male and female patients greater than 40 years of age sustaining a femoral neck fracture of intertrochanteric fracture presenting to the BAMC Orthopaedic Surgery Service within 48 hours of injury and requiring operative intervention without a history of prior deep venous thrombosis, without concomitant lower extremity precluding the use of a foot pump, not on warfare in therapy for other medical problems, and not pregnant will be eligible for inclusion in the study.

Progress: Seventy-five patients enrolled on study but not enough for achievement of statistical signs.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-47 Status: Completed

Title: Acute Normovolemic Hemodilution: Comparison of the Use of Mixed Venous Oxygen Saturation to a Standard Technique

Start date: 1 Apr 93	Estimated completion date:
Principal Investigator: CPT Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$33,386.00

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate a standard technique of hemodilution with regard to cardiovascular changes and compare this information to the safe limits of hemodilution which we will establish. 2) To establish the limits of safety of this technique based on recognized physiologic parameters by using mixed venous oxygen saturation as a guide to limit the amount of blood removed and to guide the need for transfusion therapy.

Technical Approach: Written informed consent will be obtained from the parents of 20 healthy patients scheduled for major spine surgery. A routine preoperative assessment will be performed by the anesthesia team and preoperative laboratory tests will be obtained. All patients will have anesthesia induced via mask with oxygen, nitrous oxide and halothane or with the intravenous agent thiopental. Intubation will be facilitated by the use of vecuronium bromide at a dose of 0.1 mg/kg.

Progress: Data has been completed and manuscript nearly completed. A finished copy will be forwarded when complete.  
 Apr 95: Completed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-57 Status: Ongoing

Title: Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate.

Start date: 14 Apr 92	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): COL Moo Cho, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the association of PIN and AAH with subsequent development of CAP in men with benign prostatic hyperplasia (BPH).

Technical Approach: The slides of the pathologic evaluation of the benign glands in the 333 men who underwent TURP for BPH between 1980 and 1983 will be recovered. The slides will then be forwarded to Dr. Michael Brawer at the University of Washington for evaluation. The evaluation will be made in a 'blinded' manner - i.e., Dr. Brawer will not be aware of which patients subsequently developed carcinoma of the prostate.

Progress: Same status. This study still has yet to be activated. We are currently awaiting support from the VA Cooperative Trials group for pathologic processing.

4/95: Status remains unchanged.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-66 Status: Terminated  
 Title: Impact of Dietary Manipulation on Prostate Cancer

Start date:	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Barbi Helfrick, RN Susan Wise Wilson, MS, RD, LD Forrest Newman, LTC, MC Jean M. Johnson, Ph.D., RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if a low fat, high fiber diet reduces serum prostatic specific antigen (PSA) in patients with carcinoma of the prostate. 2) To assess the impact of a low fat, high fiber diet on a patient's quality of life. 3) To assess the relationship between health beliefs, self-efficacy, social support and compliance with a low fat, high fiber diet.

Technical Approach: Pilot study will describe the impact of dietary manipulation on serum PSA, the factors which may contribute to dietary compliance, and the overall effect on quality of life. Subjects will be their own controls. The study group will consist of thirty men with known carcinoma of the prostate identified through the Urology Service Tumor Registry and who have (1) stable disease, (2) intact hormonal axis, and (3) elevated PSA (greater than 4 ng/ml as measured by the Hybritech assay). All men will be informed as to the nature of the study and will sign informed consent.

Progress: Currently there are 16 patients enrolled. Nine patients have completed the entire series.

95: PI requested termination.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-74 Status: Completed

Title: A Preliminary Study on Multiple Linear Regression Analysis of Apnea Indices as a Function of Cephalometric Measurements in Preoperative and Postoperative Patients

Start date:	Estimated completion date:
Principal Investigator: LTC Sylvester Ramirez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date:  
 Periodic review date: Aug of ea yr Review results:

Objective(s): A preoperative cephalogram and polysomnogram will be obtained in adult patients and compared to published norms.

Technical Approach: As part of their evaluation at the sleep clinic at BAMC, patients undergo a workup consisting of a history and physical, spirometry, TFTs, ABGs, cephalometric analysis and polysomnography. This is a preliminary study and thirty patients will be chosen who have OSA by polysomnography and choose surgical therapy.

Progress: Study ongoing as part of sleep study protocol C-92-81.

Aug 95: Thirty patients' cases were reviewed with preoperative and post-operative Cephalograms. These patients underwent septoplasty, tonsillectomy, uvulopalantalpharyngoplasty and/or hyoid suspension. The greatest changes in Cephalograms were noted in the hyoid suspension surgeries. Draft has been prepared for publication. The study is complete except for final statistical review.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-23 Status: Ongoing

Title: Phase III Trial of Coumarin (1, 2, -Benzopyrone) in Patients with Clinically Localized Prostatic Carcinoma Treated by Radical Prostatectomy Found Pathologically to Have High Risk of Recurrence

Start date: Jan 93	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Jan of ea yr Review results:

Objective(s): The objectives of this Phase III study of Coumarin (1,2-benzopyrone) in patients with carcinoma of the prostate treated by radical prostatectomy who are at high risk of recurrence are to:  
 1. Determine whether coumarin therapy prevents progression or delays time to progression compared to placebo.  
 2. Evaluate the qualitative and quantitative toxicities of coumarin administered for prolonged periods.

Technical Approach: The coumarin therapy including drug information details, eligibility criteria, descriptive factors, pretreatment evaluation and treatment plan are outlined in protocol.

Progress: Status remains the same. No further patients accrued.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-29 Status: Completed

Title: Heart Valve Allograft CryoLife Cardiovascular, Inc. Non-Primary Clinical Protocol

Start date: 19 Dec 92	Estimated completion date:
Principal Investigator: Greg Bowman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s): David J. Cohen, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: \$25,000.00
Number of subjects enrolled during reporting period: 2	
Total number of subjects enrolled to date: 7	
Periodic review date: Review results:	

Objective(s): To develop the safety and efficacy data for the cryopreserved heart valve allograft which will support FDA approval for the continued distribution of these heart valves as a replacement or a treatment for diseased, damaged, malformed, or malfunctioning aortic or pulmonary heart valves.

Technical Approach: Patient population, inclusion/exclusion criteria and further specifics are in protocol.

Progress: Since the last periodic review date, two additional patients have been enrolled in the study. Their procedures were performed without complications and the allografts are functioning well in short term followup. No problems related to the allografts have been identified in followup of any of the patients currently enrolled.

ADDENDUM: 25 Oct 94 - Dr Cohen reported that on 7 Oct 94, the US District Court for Northern District of Illinois accepted a settlement of the allograft heart valve litigation in which the FDA agreed to rescind its premarket approval requirements for allograft heart valves. As a result, allograft heart valves are no longer subject to the Investigational Device Exemption (IDE) requirements mandated on June 26, 1991 and enforced on November 30, 1992. This means that the valves are no longer considered to be investigational and that Institutional Review Board (IRB) approval, investigational informed consent and additional patient follow-up are no longer required.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-32 Status: Ongoing

Title: Evaluation of Gastroesophageal Reflux in Preterm Infants

Start date: 1 Jan 93	Estimated completion date:
Principal Investigator: (See below)	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Judith O'Connor, M.D. Howard Heiman, M.D. Deborah M. Burton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether gastroesophageal reflux (GER) can be reliably evaluated in intubated premature neonates. Sequential cases will be considered for inclusion in the study. The study population will consist of mechanically ventilated infants approximately 25-36 weeks gestational age.

Technical Approach: The proposed study will prospectively examine premature neonates in the 25-36 week gestational age range who meet the inclusion criteria. Inclusion criteria are infants requiring mechanical ventilation and tolerating enteral feeding. Exclusion criteria are full term infants, infants with symptoms associated with GER, infants with craniofacial disorders, neuromuscular disorders, syndromes associated with GER, or processes that mimic GER such as food intolerance, malabsorption, renal or infectious problems. Further details covered in protocol.

Progress: No results available at this time. Principal investigator has PCS'd from BAMC and protocol has not been assigned to another PI. Study remains ongoing.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-42 Status: Completed

Title: A Comparison of Six Different Intraoperative Site Determinations of Body Temperature Compared to Core Blood Temperature

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Scott T. Davis, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative	Associate Investigator(s): Richard B. Hecker, M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 53  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Patients undergoing surgical procedures are at risk for thermal perturbations. Most patients become hypothermic during surgery, although a few become hyperthermic. Temperature changes in either direction can be a cause of complications requiring treatment. The best technique for accurate measurement of intraoperative temperature remains a point of controversy. The objective of this study is to compare seven methods for noninvasive monitoring of body temperature: Tympanic, esophageal, oral, bladder, nasopharyngeal, rectal and forehead skin temperatures against core blood temperature as measured from the pulmonary artery.

Technical Approach: This study will compare the accuracy and precision of seven methods for monitoring body temperature in the operating room. Tympanic temperatures will be recorded utilizing an infrared sensitive electronic tympanic probe. Esophageal temperatures will be measured using an esophageal stethoscope/temperature probe placed in the distal esophagus. Further specifics outlined in protocol.

Progress: Commonly employed temperature measurement modalities used for making intraoperative decisions based upon estimated core body temperatures poorly agree with PAT measurements. Therefore, decision making criteria should be instrument specific. Significant underestimation of pulmonary artery core temperatures are noted with ET, NT, LCT and OT. Of the noninvasive methods, RT and ITT most closely agree with PAT. Abstract written.

Aug 95: Completion requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-48 Status: Ongoing

Title: Clinical Evaluation of Left Ventricular Assist Device

Start date: 12 Mar 93	Estimated completion date:
Principal Investigator: David J. Cohen, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): This study is designed to evaluate the use of a Pierce-Donachy Paracorporeal Ventricular Assist Device for patients with one of three problems: 1) post open heart surgery cardiac failure, 2) post myocardial infarction cardiogenic shock, and 3) cardiomyopathy when patients are awaiting heart transplantation and no donor hearts are available. This device is intended for use in patients with heart failure who would otherwise be unable to be supported through conventional medical means. The device would be used for a relatively short period (two to ten days) until either cardiac function returns to a level sufficient to allow for device removal or, in the case of "bridge to transplant," until a donor heart is available. If approval of this project is obtained, we hope to be named an investigational site by the Thoratec Corporation under agreement with the Food and Drug Administration.

Technical Approach: Outlined in protocol.

Progress: Protocol has not been activated. We still await funding.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-51 Status: Ongoing

Title: Mandibular Reconstruction by Distraction Osteogenesis

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Sylvester G. Ramirez, M.D.	Facility: Wilford Hall AFMC Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Peter D. Costantino, M.D. USAF
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Reconstruct segmental mandibular defects in selected human subjects by applying distraction osteogenesis; and 2. Critically evaluate the efficacy of distraction osteogenesis for mandibular reconstruction in humans as compared to standard techniques.

Technical Approach: Methods, significance, risk/benefit ratio, and other specifics outlined in protocol.

Progress: To date no patients have been entered at BAMC. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-68 Status: Ongoing

Title: Intraincisional Bupivacaine and Intramuscular Ketorolac for Post-operative Pain Relief After Laparoscopic Bilateral Tubal Electrofulguration

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Christina L. Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): Julius Szigeti, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 60  
Total number of subjects enrolled to date: 75  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the post-operative pain relief after operative laparoscopy and bilateral tubal electrofulguration (BTF) using intramuscular (IM) ketorolac alone, ketorolac with intraincisional bupivacaine and intraincisional bupivacaine alone. The total number of patients studied will be 128 (32 in each of the above groups plus a control group who will receive no study drugs). All patients will be American Society of Anesthesiologists (ASA) physical status I or II.

Technical Approach: Details including anesthesia, laparoscopic technique, pain evaluation and statistical analysis are outlined in protocol.

Progress: We are still enrolling patients. Data collection continues.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-76 Status: Completed

Title: Phase I/II Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Cancer of the Prostate

Start date: 13 May 93	Estimated completion date:
Principal Investigator: Ian Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Peter Ravdin, M.D., UTHSCSA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 7  
 Periodic review date: May of ea yr Review results: Completed

Objective(s): To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer, and to compare the effects of 2 immunization schedules. To determine if immunization against LHRH will cause suppression of luteinizing hormone (LHL) and follicle stimulating hormone (FSH) levels in men who have castrate testosterone levels, and cause a decrease in testosterone levels in men who have not undergone orchiectomy. To observe patients for signs of adverse effects following immunization.

Technical Approach: Protocol covers all specifics. It should be noted that all laboratory specimens will be obtained and assayed at UTHSCSA and no assays will be performed at BAMC. All immunizations will be performed at UTHSCSA. Additionally, it must be noted that although a total of 30 patients will be accrued to this protocol, this number is a total of both participating institutions.

Progress: A total of 7 patients have now been entered into this 2nd of the LHRH - TT protocols. It is currently closed and data are being analyzed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-78 Status: Ongoing

Title: The Use of EEG and Hemodynamic Parameters in the Design of Intelligent Anesthetic Control Systems

Start date: 14 May 93	Estimated completion date:
Principal Investigator: Douglas Anderson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op	Associate Investigator(s): Paul Mongan, M.D. John Ward, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: May of ea yr Review results:

Objective(s): This study will collect hemodynamic and physiologic data in conjunction with raw EEG and Auditory evoked Responses from patients undergoing general anesthesia for surgical procedures. This data will be analyzed off-line for correlations of EEG changes with hemodynamic changes that are interpreted clinically as changes in anesthetic depth. Utilizing this information, signal processing techniques, adaptive control theory and artificial intelligence concepts will be applied to develop a anesthesiologist in providing patient care.

Technical Approach: This study is descriptive in nature and seeks only to assemble a data base of patient data for future study and analysis.

Progress: There has been no progress in this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-93 Status: Terminated

Title: Determination of Preoperative Intravascular Volume Deficit in Bowel-Prepped Surgical Patients

Start date: 1 Jul 93	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 20  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if oral bowel prep solutions as administered routinely prior to abdominal surgery, reduce intravascular volume in the adult surgical patient before surgery. Null hypothesis: Oral bowel preparation has no effect on preoperative intravascular volume status.

Technical Approach: 40 ASA physical status 1-3 patients, ages 18-65, presenting for elective surgical procedures will be enrolled in the study after written consent is obtained. Further specifics given in protocol.

Progress: No additional patients enrolled secondary to scholastic/professional demands (i.e., Boards) and concomitant difficulty with technique (difficult to reliably maintain butterfly in peripheral vein for both injection and withdrawal at timed intervals). No sampling difficulty encountered with protocol C 94-18 (via 4-line) but this study not approved for preop 4-line placement. No additional funding requirements anticipated for FY 95.

Jul 95: No additional patients enrolled/no adverse effects encountered. Study terminated due to technical difficulaies documented above - will not seek to continue study as previous data is questionable given sampling problems encountered and attempting to revise protocol to allow for 4-line sampling would be logistically difficult.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-91 Status: Ongoing

Title: Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Maurice Albin, ND
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of air and particulate emboli during cardiopulmonary bypass (CPB) using transcranial doppler ultrasound as a detection device and to detect, correlate, and follow postoperative neurologic and psychometric changes seen in patients.

Technical Approach: This is a multicenter outcome study with UTHSCSA and Wilford Hall Medical Center. 125 patients requiring CPB will be enrolled with 25 patients for peripheral vascular procedures not requiring CPB serving as controls. Psychologic testing and neurologic evaluation will be performed preoperatively, at discharge and at 6 weeks, 6 months and 1 year after discharge. Intraoperative noninvasive testing will consist of transcranial doppler ultrasound (TCD) for the detection of air and particulate emboli and EEG monitoring by a commercially available processed EEG monitor. Anesthetic regimens will be standardized.

Progress: We are still awaiting funding by NIH.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-113 Status: Completed

Title: Effects of Desflurane on the Amplitude and Latency Characteristics of Brainstem Auditory, Midlatency Auditory, Median and Posterior Tibial Nerve Evoked Potentials

Start date: Aug 93	Estimated completion date:
Principal Investigator: Paul D. Mongan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the effect of desflurane on the amplitude and latency characteristics of multimodality sensory evoked potentials.

Technical Approach: Study design, population, methods and specifics covered in protocol.

Aug 95: Patient enrollment complete; doing data analysis.

Progress: We anticipate completion of this study by December 1994.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-120 Status: Ongoing

Title: Menstrual Cycle Impact Upon Breast Cancer - Women - Surgery Balance

Start date: Aug 93	Estimated completion date:
Principal Investigator: Johnny Alvarez, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/General Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): The prospective observational study described by this protocol will carefully document the menstrual cycle stage of breast cancer or benign breast biopsy and/or breast cancer resection and measure cellular and humoral activities known or suspected to affect metastatic potential in patient samples obtained before and following that biopsy and/or resection.

Technical Approach: Study design, treatment plan/flow, clinical evaluation/follow-up, and specifics outlined in protocol.

Progress: Awaiting final MRDC approval.

Aug 95: Just received funding; no patients enrolled yet.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-01 Status: Ongoing

Title: Magnitude of Hypotension With and Without Intravenous Fluid Preload in Healthy Patients Receiving Subarachnoid Anesthesia

Start date: 1 Oct 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s):
Key Words: Subarachnoid Anesthesiology Hypotension	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 150  
Total number of subjects enrolled to date: 150  
Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the magnitude of hypotension in healthy patients undergoing subarachnoid anesthesia with and without a fluid preload. The total number of patients studied will be one hundred fifty.

Technical: It is hypothesized that there will be no difference in the magnitude of blood pressure drop with or without fluid preload in patients receiving SAB. One hundred and fifty patients will be enrolled to obtain statistical significance. Criteria for inclusion and other specifics are outlined in protocol.

Progress: Oct 95: Study completed; Analysis and writing of report pending completion.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-05 Status: Ongoing

Title: Oral Atropine Premedication in Children: Effects on Airway and Respiratory Events During General Anesthesia for PE Tube Placement

Start date: Oct 93	Estimated completion date:
Principal Investigator: Douglas Anderson, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Hunter Richmond, M.D. Kim Cantees, M.D. Ken Azarow, M.D. James Redwine, CRNA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 140  
Total number of subjects enrolled to date: 140  
Periodic review date: Oct of ea yr Review results:

Objective(s): Determine the effect of oral atropine premedication on reducing significant airway and respiratory events during the induction, maintenance, and recovery in children undergoing general anesthesia for PE tube placement.

Technical Approach: Study design including hypothesis, statistical analysis and details are included in protocol.

Progress: Continuing to evaluate. Oct 95: Predict to finish in a few months.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-09 Status: Ongoing

Title: The Incidence of Concomitant Leg and Foot Compartment Syndrome

Start date:	Estimated completion date:
Principal Investigator: James A. Dahl, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Nov of ea yr Review results:

Objective(s): To determine the incidence of foot compartment syndrome concurrent with leg compartment syndrome.

Technical Approach: The patients would be drawn from the population treated at BAMC and would consist of any patients presenting for evaluation and treatment of tibial fractures or suspected acute leg compartment syndrome. Specifics are given in protocol.

Progress: Haven't had anyone eligible during last year.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-18 Status: Ongoing

Title: Determination of Perioperative Intravascular Volume Status in TURP Patients Under Subarachnoid Anesthesia

Start date: 16 Dec 93	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Operative Svc	Associate Investigator(s): Brian Thwaites, M.D.
Key Words:	Douglas M. Anderson, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To determine and qualify perioperative changes in intravascular volume status secondary to absorption of irrigation solution during TURP.  
 Null hypothesis: No detectable changes in perioperative intravascular volume occur during TURP.

Technical Approach: 50 ASA 1-3 patients, age 18-90 presenting for elective transurethral procedures under subarachnoid anesthesia will be enrolled. Group A will consist of 25 patients undergoing TURP; Group B will be a control group of similar number whose transurethral procedure does not involve prostatic resection. Resection of bladder tumors with irrigation will be deemed acceptable for Group B as substantial absorption of irrigation from bladder tissue has not been demonstrated.

Progress: Four patients enrolled to date but anticipate accelerated enrollment as Urology caseload increases. No preliminary conclusions thus far due to early point in study. No patient complications experienced thus far.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-20 Status: Ongoing

Title: The Use of Urine Cytology for the Early Diagnosis of Transitional Cell Carcinoma of the Bladder in High Risk Patients

Start date: Dec 93	Estimated completion date: Dec 94
Principal Investigator: Douglas A. Schow, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
Total number of subjects enrolled to date: 23  
Periodic review date: Dec of ea yr Review results: See below

Objective(s): To determine the yield of urinary cytology in the early detection of bladder cancer.

Technical Approach: If the positive predictive value of voided urinary cytology should prove to detect patients with bladder cancer with high specificity, high risk groups (cigarette smokers, individuals with exposures to known urothelial carcinogens) may consider early detection to reduce mortality and morbidity from bladder cancer.

Progress: 1 patient: (+) hematuria, (-) urine cytologies  
IVP(-), cysta - local dysplasia by TURBT  
1 patient: (+) hematuria, (-) urine cytologies, (-) cystoscopy  
Mass on IVP - CT Scan - complete cyst - will be followed by renal U/S  
9 patients: (+) hematuria, (-) urine cytologies, (-) IVP, (-) cystoscopy  
7 patients: (-) U/A, (-) urine cytologies

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-21 Status: Ongoing

Title: A Prospective Study Evaluating Optimal Volume of Blood Injected into the Epidural Space for Treatment of Post Dural Puncture Headache

Start date: Dec 93	Estimated completion date: 20 Sep 94
Principal Investigator: Marc Boin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Sam Sayson, M.D.
Key Words: Anesthesia, Post dural puncture headache, regional anesthesia, complications	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: Dec of ea yr Review results: No difference

Objective(s): To assess, in a prospective manner, the optimal volume of blood to be injected into the epidural space for relief of post dural puncture headaches. To compare the effects of using a predetermined volume of epidurally injected blood versus a volume of blood which is titrated to patient tolerance in the relief of PDPH.

Technical Approach: Null Hypothesis - There is no difference in failure rate of epidural blood patch for treatment of PDPH when a volume of 5, 10, 15cc of blood is used. Study population, data collection and statistical analysis included in protocol.

Progress: PI has left BAMC. Patient population with post dural puncture headaches has decreased. Study population is too small at this time to evaluate hypothesis.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-28 Status: Ongoing

Title: Clinical Evaluation of Low Dose Heparin in Conjunction with a Heparin Coated Circuit for Cardiopulmonary Bypass

Start date: 11 Jan 94	Estimated completion date:
Principal Investigator: Greg Bowman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To test the safety and efficacy of lower dose heparinization (100 units/kg) in conjunction with a covalently bonded heparin coated (DuraFlow™, Edwards Labs) cardiopulmonary bypass circuit in patients undergoing cardiac surgery.

Technical Approach: A randomized, prospective analysis of patients undergoing elective coronary artery bypass surgery. Blood samples will be drawn preoperatively, after heparinization but before bypass, at 30 minute intervals during bypass, and 30 minutes after protamine administration. These samples will measure ACT, fibrinopeptide A, platelet count, serum hemoglobin, and fibrinogen. Bleeding time, prothrombin time, partial thromboplastin time, and thrombin time will be measured preoperatively, and 30 minutes and 4 hours after protamine administration. Thromboelastography will be performed preoperatively and 30 minutes following protamine administration. Following surgery the bypass circuit will be examined for macroscopic clot and the patient's mediastinal drainage will be monitored for 24 hours. Requirements for transfusions of blood and blood products will be monitored for the 24 hr perioperative period. Patients will be dropped from the study if they require the intra-aortic balloon pump, or if bypass time exceeds 4 hours. Analysis of quantitative data, presented as the mean +/- standard deviation, will be accomplished with the Student t test.

Progress: Has yet to be activated. Pending approval and receipt of funds.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-31 Status: Ongoing

Title: Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

Start date: 14 Jan 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: DACH Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesia & Operative Svc	Associate Investigator(s): Douglas M. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: ?  
 Total number of subjects enrolled to date: ?  
 Periodic review date: Jan of ea yr Review results:

Objective(s): To compare of the study is to compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

Technical Approach: Hypothesize: 1. The paramedian aproach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle. 2. The paramedian approach using the Quincke needle is associated with less PDPH than the midline Quincke method. 3. The paramedian approach using the quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Total number of subjects required for statistical significance is estimated to be 200.

Progress: Dr. Szigeti has transferred to Darnall ACH and the study will be basically done there.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-33 Status: Ongoing

Title: The Effect of Transexamic Acid When Given After Cardiopulmonary Bypass and Its Correlation with Thromboelastography

Start date: 21 Jan 94	Estimated completion date:
Principal Investigator: Ron Brannon, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): Will Transexamic Acid (TA) prove to be beneficial after cardiopulmonary bypass (CPB) routinely or in a subgroup of patients with an abnormal thromboelastography (TEG)?

Technical Approach: Patients will be ASA III-IV patients scheduled for elective nonemergeney coronary bypass or valve operation with extracorporeal circulation. All patients will have normal preoperative coagulation profiles and be between the ages of 18 and 80. Exclusion criteria, transfusion criteria and data collection data included in protocol.

Progress: No data available.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-41 Status: Ongoing

Title: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Versus TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

Start date: 28 Jun 94	Estimated completion date:
Principal Investigator: Mary O'Hara, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jun of ea yr Review results:

Objective(s): The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reations for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivities. Acute is defined as having a duration of one week or less.

Technical Approach: Materials/methods, subjects, study procedure, statistical evaluation, etc., furnished in protocol.

Progress: Alcon has decided to pursue study at fewer medical centers. Therefore BAMC is an alternate site.  
 May 95: Study never began at our facility.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-46 Status: Ongoing

Title: A Study of the Ability of Anesthesiologists and Surgeons to Differentiate Arterial from Central Venous Blood Samples by Visual Inspection of Hue

Start date: 8 Feb 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op	Associate Investigator(s): Van Garman, M.D. Paul D. Mongan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine whether it is possible for physicians familiar with central line placement are able to differentiate arterial from venous source by visual inspection of the blood in a syringe. The blood will be drawn from arterial lines and internal jugular vein catheters at four different fractional inspired oxygen concentrations to simulate those concentrations most frequently used in the operating rooms. They will be analyzed under low light and bright light conditions by anesthesiologists and surgeons.

Technical Approach: This is a descriptive study which will determine the positive predictive value of a visual inspection of hue to determine blood source. Ten patients who require arterial line and central venous catheter placement for their surgery will be enrolled and informed consent will be obtained. After intubation, each patient will be placed on four different FIO<sub>2</sub> (21%, 30%, 50% and 100% for 10 minutes and then a 1.5cc sample of arterial and central venous blood will be aspirated into a blood gas syringe. Further details in protocol.

Progress: None at this time.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-52 Status: Ongoing

Title: Incident of Post-dural Puncture Headaches with Continuous Spinal Anesthesia and 24 Gauge Catheter Over 26 Gauge Needle

Start date: 11 Feb 94	Estimated completion date:
Principal Investigator: R. Scott Brown, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Anes & Op Svc/Surgery	Associate Investigator(s): Philip J. Becker, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the incidence of posdural puncture headache (PDPH) with the new Johnson-Bittner 26 gauge needle with which a 24 gauge catheter is passed over the top for continuous spinal anesthesia (CSA) in patients at high risk for PDPH (age 18-40).

Technical Approach: It has been proposed that incidences of PDPH with large bore catheters and needles and CSA is 70%. This study will theoretically lower this incidence by using a smaller needle (26 gauge) and tight fitting catheter (24 gauge) to reduce CSF leakage and will avoid complications of cauda equina syndrome by avoiding the use of a microcatheter, 5% lidocaine and any hyperbaric solutions. Patient evaluation, symptoms and specifics are outlined in protocol.

Progress: Study progressing well. There is no data to report at this time.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-61 Status: Ongoing

Title: Peritoneal Irrigation in Gunshot Wounds of the Abdomen

Start date: 4 Mar 94	Estimated completion date: 30 Jun 95
Principal Investigator: John J. Kelemen, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Gen Surg	Associate Investigator(s): James Obney, M.D. R. Russell Martin, M.D.
Key Words:	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 12  
Total number of subjects enrolled to date: 12  
Periodic review date: Mar of ea yr Review results:

Objective(s): To correlate cell count values for peritoneal irrigation with physical examination, peritoneal penetration and the extent of injury in gunshot wounds to the abdomen.

Technical Approach: Description of subjects and controls: All individuals brought to BAMC with a gunshot wound to the abdomen. Since the majority of patients with gunshot wounds to the abdomen have a visceral injury, it is estimated that a large number of subjects (200) will be required to generate a non-visceral injury group of sufficient size to attain statistical significance. Experimental design/methods: Exploration celiotomy is currently performed on all patients with gunshot wounds to the abdomen at BAMC. This practice will not be significantly changed or delayed. At the initiation of celiotomy, in stable patients, the abdomen will be lavaged with 1000cc of lactate ringer's solution and a cell count will be performed on the fluid return. The operating surgeons will be blinded from the results of lavage analysis during the operation. Data collection and statistical analysis outlined in protocol.

Progress: No adverse consequences. Initial results suggest DPL is an excellent discriminator.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-62 Status: Ongoing

Title: The Effect of Intravenous Ketorolac on Platelet Function During General Anesthesia

Start date: 10 Mar 94	Estimated completion date: Sep 94
Principal Investigator: Brian K. Thwaites, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Daren Nigus, M.D. Gregory W. Bouska, M.D. Paul Mongan, M.D. Gerald Merrill, Ph.D. Eleanor Ayala
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 28  
Total number of subjects enrolled to date: 28  
Periodic review date: Mar of ea yr Review results:

Objective(s): To determine whether ketorolac given intravenously has significant effects on platelet function during general anesthesia.

Technical Approach: Prior studies demonstrate inhibition of platelet function in awake volunteers in the form of prolonged bleeding times and diminished platelet aggregation studies. Other studies demonstrate that under general anesthesia, platelet function is enhanced and that the production of thromboxane B2 is enhanced. To date, the net effect of general anesthesia and IV ketorolac has not been studied.

Progress: Nearing completion.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-73 Status: Ongoing

Title: Sore Throat with the Laryngeal Mask Airway in Pediatric Patients - The Effect of Lubrication

Start date: 25 Mar 94	Estimated completion date: Mid 96
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Samuel C. Sayson, M.D. Jason P. Fontenot, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligible patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine jelly.

Technical Approach: Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc, included in protocol.

Progress: Number of pediatric patients meeting criteria is limited. Plan to have Arkansas Childrens Hospital cooperate with study to increase numbers.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-74 Status: Ongoing  
 Title: Sore Throat with the Laryngeal Mask Airway - The Effect of Lubrication

Start date: 1 Apr 94	Estimated completion date: Dec 95
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Samuel C. Sayson, M.D. Jason P. Fontenot, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: Approx 10  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligible patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine jelly.

Technical Approach: Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc, included in protocol.

Progress: Have only enrolled two patients in months since last review secondary to TDYs and other military assigned duties. Plan to continue to enroll patients but am again being sent on an extended TDY to backfill soon.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-76 Status: Ongoing

Title: Rocuronium onset of action: An EMG dose response study of the adductor pollicis, orbicularis oculi and the adductor muscles of the larynx

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Paul Mongan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Sam Sayson, M.D. Scott Brown, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the onset of action and depth of blockade at the adductor pollicis, orbicularis oculi and the muscles of the larynx. To determine the difference in onset of action and depth of blockade with 2X, 3X and 4X an ED95 dose of rocuronium bromide.

Technical Approach: Null hypothesis, technical validity of procedures, study design, inclusion/exclusion criteria included in protocol.

Progress: No progress.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-77 Status: Completed

Title: Comparison of Apraclonidine (Iopidine) 1% and 0.5% in Intraocular Pressure Control After Argon Laser Trabeculoplasty in Patients with Primary Open Angle Glaucoma

Start date: 5 Apr 94	Estimated completion date: 30 Nov 94
Principal Investigator: David R. Rivera, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s): John A. Campagna, M.D. (Staff)
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50  
Total number of subjects enrolled to date: 50  
Periodic review date: Apr of ea yr Review results:

Objective(s): The study purpose is to assess if apraclonidine (Iopidine) 0.5% will have the same or similar effect on accurate intraocular pressure changes after argon laser trabeculoplasty as the standard 1% apraclonidine.

Technical Approach: The hypothesis is that 05% apraclonidine will control IOP elevations as well as 5% after ALT surgery. To ascertain this, a double blind study is proposed in which primary open angle glaucoma (POAG) patients who have ALT will be invited to participate. A Coherent 920 tunable dye Argon laser is used with settings of 0.1 sec pulses and 50 micron spots of Argon green laser. Laser power is typically between 400 and 1000 milliwatts and titrated in each individual patient to obtain the desired effect of mild to blanching tissue at the photocoagulation site. Detailed specifics included in protocol.

Progress: To date there have been no adverse reactions to either concentration of apraclonidine. Both concentrations have presented intraocular pressure spikes. No patient has had an intraocular pressure spike above 10 mmHg.

4/95: Significant findings reached at 50 patients, study completed.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-78 Status: Ongoing

Title: Survival and Morbidity Tradeoffs in Prostate Cancer Treatment - Impact of Patient Perspective

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Jean M. Johnson, PhD, RN Barbi Helfrick, BSN, RN Douglas Schow, M.D. Leonard Renfer, M.D. Julius L. Teague, M.D. John Ward, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To compare men with different prostate cancer conditions on their choice of treatment, factors which influence treatment choices, and perceptions about treatment risks and benefits. To examine the relationship between the maximum acceptable risk for the minimal acceptable benefit of treatment. To identify the best predictors of treatment choice. To examine the relationship between decision style and treatment choice.

Technical Approach: A descriptive study will be done to compare five groups of men with different prostate cancer conditions in regard to their decision for treatment when survival and morbidity tradeoffs are considered. Specific subject groups, data collection methods, instruments, data analysis, etc., included in protocol.

Progress: Enrollment continues and questionnaires are currently being mailed to patients.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-80 Status: Ongoing

Title: Clinical evaluation of correlation between Thoracic Bioimpedance and thermodilution Cardiac Output Determinations

Start date: 7 Apr 94	Estimated completion date: April 95
Principal Investigator: Gerald R. Harrington, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Surgical Intensive Care Unit	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To perform an independent scientific clinical evaluation of a new noninvasive monitor of cardiovascular function compared to the current "gold standard" technique of thermodilution cardiac output determinations.

Technical Approach: All adult patients who undergo elective placement of a pulmonary artery catheter will be eligible for inclusion in the study. Patients will have cardiac output determined simultaneously by thermodilution and bioimpedance during the course of their routine care in the Ward 13A SICU. Further specifics are outlined in protocol.

Progress: Correlation between TD and bioimpedance fair in first few patients.

4/95: With the data collection from all of the sites over the first year, the company producing the BI monitor upgrade the software approximately one month ago. The new software performs remarkably well even in those patients in whom it previously was unreliable. As the new software has only been in place for a short period, the study is ongoing. Therefore I have enrolled two patients with the new software in place.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-81 Status: Ongoing

Title: Mechanical Characteristics of the Femoral Intramedullary Nailing Systems Available from Five Different Manufacturers

Start date: 7 Apr 94	Estimated completion date:
Principal Investigator: Keith D. Wilkey, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopedic Surgery	Associate Investigator(s): William Mehserle, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Apr of ea yr Review results:

Objective(s): To determine the mechanical characteristics of five commonly used femoral intramedullary nails. We will examine, in vitro, the stiffness (rigidity), strength, and fatigue characteristics of the entire device, including the majority of the proximal and distal ends. A range of values regarding the strength, stiffness, and fatigue strength will be obtained. Superior and inferior designs will be identified.

Technical Approach: Literature review summary, medical application, materials/methods, etc., outlined in protocol.

Progress: The mechanical part of the study is complete at this point. Awaiting additional funding for additional material.

4/95:

1. Have obtained additional funding - obtained 5 more nail types (total of 8).
2. Will complete laboratory portion of study within 1 month.
3. Data analysis to follow.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-93 Status: Ongoing

Title: A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14-valerate (AD 32) in Patients with Cell Carcinoma in situ of the Bladder Who Have Failed or Have Recurrence Following Treatment with Bacillus Calmette-Guerin

Start date: 9 May 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Service	Associate Investigator(s): Leonard Renfer, MC Cathy Pollard, RN Douglas A. Schow, MD Barbi Helfrick, RN
Key Words: Intravesical AD 32	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: May of ea yr Review results:

Objective(s): To assess the efficacy of intravesical instillations of AD 32 and to evaluate the quantative toxicities associated with it.

Technical Approach: After determining by physical exam and microscopic examination of the urine that the patient does not have a urinary tract infection, 4 vials of the study drug are diluted and infused into the patient's bladder, using aseptic technique. The patient is instructed to hold the medication for at least 2 hours. This procedure is repeated at weekly intervals x 6.

Progress: No appropriate candidates have been enrolled into this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-94 Status: Ongoing

Title: A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14-valerate (AD 32) in Patients with Transitional Cell Carcinoma of the Bladder

Start date: 9 May 1994	Estimated completion date:
Principal Investigator: Iam M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Service	Associate Investigator(s): Thomas A. Rozanski, MD Douglas Schow, M.D.
Key Words: Intravesical AD 32	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: May of ea yr Review results:

Objective(s): To assess the efficacy of intravesical instillations of AD 32, to evaluate the qualitative and quantitative toxicities associated with it and to evaluate qualitative information on efficacy and toxicity associated with 6 installations versus 9.

Technical Approach: After determining by physical exam and microscopic examination of the urine that the patient does not have a urinary tract infection, 4 vials of the study drug are diluted and infused into the patient's bladder, using aseptic technique. The patient is instructed to hold the medication for at least 2 hours. This procedure is repeated at weekly intervals x 6 in half the patients and x 9 in half the patients.

Progress: No appropriate candidates have been enrolled into this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-96 Status: Terminated

Title: Antiemetic Effectiveness in the Post Anesthesia Care Unit  
(recovery room)

Start date: 20 Apr 94	Estimated completion date: Dec 95
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology Service	Associate Investigator(s): Robert S. Brown, M.D. Christopher J. Duggins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the effect of single agent and combination antiemetic therapy in the post anesthesia care unit after adequate pain relief is achieved.

Technical Approach: Combination antiemetic therapy is more effective than single agent therapy in postoperative patients who have had adequate pain control. Sample size: 100 total patients, 20 in each group. Description of subjects, experimental design and specifics are outlined in protocol.

Progress: Progress on this protocol has been difficult. The requirement to consent all eligible patients preoperatively has been fraught with many problems. Only approximately 50% of patients are being consented. The requirement for the pharmacy service to draw up blinded drugs has also met with difficulty as PI is usually still involved with clinical duties during duty hours, therefore it is difficult to pick up the drugs at another hospital. In addition it appears that the incidence of nausea is less than that reported by the PACU nurses (at least when the objective criteria of the study are applied). Drs Brown, Mongan and PI plan to reevaluate this study in the next few weeks and determine its continued feasibility.

4/95: It has been decided by PI and Drs Brown and Mongan that this study is not feasible at this institution. We plan to terminate this study.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-108 Status: Ongoing

Title: Survey of Current Opinion on the Diagnosis and Treatment of Suspected Intraoperative Malignant Hyperthermia

Start date: 23 Jun 94	Estimated completion date:
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Service	Associate Investigator(s): Richard Hecker, D.O. Robert Oldroyd, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50-75  
 Total number of subjects enrolled to date: 50-75  
 Periodic review date: Jun of ea yr Review results:

Objective(s): To survey anesthesia care providers nationwide to determine current opinion on the diagnosis, management and follow-up care of an intraoperative patient with suspected malignant hyperthermia.

Technical Approach: This study is not designed to test a hypothesis. The purpose is to determine the current opinion of anesthesia care providers on malignant hyperthermia treatment issues. Description of subjects, experiment design, data collection and statistical analysis included in protocol.

Progress: Data collection in progress. Will pole National Anesthesia Meeting participants in Sep 94. Expect completion in 1995.  
 May 95: All data sheets have been collected. Data is currently being collected and analyzed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-114 Status: Completed

Title: Determining of Effects of Intravenously Administered Ketorolac (Analgesic) on Platelet Function During Spinal Anesthesia

Start date: 7 Jul 94	Estimated completion date:
Principal Investigator: Brian K. Thwaites, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Paul Mongan, M.D. Daren Nigus, M.D.
Key Words:	
Cumulative MEDCASE cost: \$1500	Estimated cumulative OMA cost: \$1500

Number of subjects enrolled during reporting period: Approx 15  
Total number of subjects enrolled to date: Approx 15  
Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether ketorolac given intravenously has significant effect on platelet function during spinal anesthesia.

Technical Approach: Null Hypothesis - That there will be no difference in platelet function during spinal anesthesia with ketorolac when compared to baseline platelet function prior to the operation. Validity, sample size, study design and population specifics outlined in protocol.

Progress: Jul 95: Completed



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-133 Status: Ongoing

Title: Effects of Breast Cancer on Prostate Cancer Risk

Start date: 15 Aug 94	Estimated completion date:
Principal Investigator: Rhonda Cornum, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Svc	Associate Investigator(s): Ian M. Thompson, M.D. Clare Scanlon
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if the risk of prostate cancer in men with first degree (mother, daughter, or sister) female relatives with breast cancer is different from men with no first degree relatives who have breast cancer. This is an epidemiologic study. Test subjects will be first degree relatives of women who have been diagnosed with breast cancer at BAMC over the past twenty years; the control population will be first degree relatives of women who had breast biopsies but in whom no cancer was found.

Technical Approach: Description of subjects/controls, experimental design/methods, data collection, statistical analysis and further details are outlined in protocol.  
 Aug 95: Accruing information. Pending opening of study, awaiting enrollment of first patient.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-134 Status: Terminated

Title: Evaluation of the Safety and Efficacy of Transurethral Resection of the Prostate Using the Contact Laser System vs. Electrosurgery

Start date: 17 Aug 94	Estimated completion date:
Principal Investigator: Leonard G. Renfer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Iam M. Thompson, M.D. Douglas Schow, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: Terminated

Objective(s): To evaluate the effectiveness (resection and coagulation) of the contact Laser <sup>TM</sup> System in comparison to that of electrosurgery for transurethral resection of the prostate (TURP). To evaluate the safety of the Contact Laser <sup>TM</sup> System as it is used in the TURP procedure, and to compare the safety to concurrent results of the procedure involving electrosurgery. To evaluate the relative cost effectiveness of the Contact Laser <sup>TM</sup> in comparison to that of electrosurgery for transurethral resection of the prostate (TURP).

Technical Approach: Study Overview, population, plan, devices and further details are given in protocol.

Progress: Study has not yet begun; awaiting preliminary prestudy work and for people to get trained.

4/95: No subjects were placed on this study at this institution.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-139 Status: Completed

Title: Rapid Sequence Intubation with Rocuronium Bromide, Mivacurium Chloride and Succinylcholine

Start date: 8 Sep 94	Estimated completion date:
Principal Investigator: James B. Stevens, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): Patricia Reddin, M.D. John Shepherd, M.D. M. Valerie Vescovo, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 70  
 Periodic review date: Sep of ea yr Review results: Completed

Objective(s): To collect data concerning the onset, potency, duration, and termination of action of nondepolarizing neuromuscular blocking drugs for rapid sequence intubation of the trachea. Specifically, we will compare a combination dose of rocuronium bromide and mivacurium chloride to an equivalent dose of rocuronium alone. These two drugs have entirely different chemical structures and pathways of metabolism. Therefore, synergism of action and faster termination of effect are possible.

Technical Approach: This study will enroll sixty adult patients of both sexes who are ASA physical status I, II, or III and who are scheduled for elective surgery requiring general anesthesia. Exclusion criteria will include emergency surgery, pregnancy, possible difficult airway, neuromuscular disease, renal disease, hepatic disease, or prior complication related to general anesthesia. Informed consent will be obtained.

Progress: Aug 95: Study completed. Papers accepted for presentation at the American Society of Anesthesiologists, Oct 95.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-147 Status: Terminated

Title: Hydrokinetic Retinal Manipulation Using the Liquid and Viscous Fluorocarbon Perfluorophenanthrene

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Weldon A. Dunlap, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To participate in Phase 2 investigation of the intraoperative use of perfluorophenanthrene liquids to facilitate the management of complicated retinal detachment, dislocated lens fragments, dislocated intraocular foreign bodies, and other complicated surgeries in the posterior segment of the eye.

Technical approach: Perfluorophenanthrene is a heavier than water liquid which is especially useful in retinal surgery for manipulation of the retina intraoperatively. It is usually removed prior to the end of the surgery but in certain cases of complicated inferior retinal detachments has been deliberately left in the eye for periods of up to 4 weeks to maintain long term tamponade of the inferior retina. From the data collected thus far, there appears to be minimal complications from the use of perfluorophenanthrene.

Progress: This is a new study. There is no reportable data.

Mar 95: Annual Review - Termination requested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-150 Status: Terminated

Title: An Open-Label, Randomized, Parallel Group study to Compare the Safety and Efficacy of Two Dosing Regimens of PROCRIT (Epoetin Alfa) in Subjects Undergoing Major Orthopedic Surgery

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Allen Bucknell, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopedics	Associate Investigator(s): Brian Johnson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Sep of ea yr Review results:

Objective(s): To evaluate various user-convenient dosing regimens of PROCRIT in order to determine if a more user-convenient dosing regimen with lower total doses of PROCRIT produces an erythropoietic response comparable to PROCRIT 300 U/kg x 15 doses.

Technical Approach: Study population, randomization/blinding, dosage/administration and other specifics outlined in protocol.

Progress: This is a new study. There is no reportable data.  
Aug 95: Dr. Bucknell recommends termination.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-152 Status: Terminated

Title: A Pilot Study to Evaluate the Histologic Response to the CDDP-e Therapeutic Implant (MPI 5010) Administered Prior to Radical Prostatectomy in Patients with Stage A, B or C Prostatic Carcinoma

Start date: Sep 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Ian M. Thompson, M.D. Douglas Schow, M.D. Leonard Renfer, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Sep of ea yr Review results: Terminated

Objective(s): To evaluate the histologic response following administration of the CDDP-e TI when administered prior to radical prostatectomy in patients with Stage A, B or C prostate carcinoma. To determine effective dose levels of the CDDP-e TI and to investigate the potential antitumor effect for local disease control.

Technical Approach: Study criteria and specifics are outlined in protocol.

Progress: May 95: Terminated - no appropriate candidates were placed on this protocol.

# Detail Summary Sheet

Date: 1 Dec 95

Protocol Number: C-95-02

Status: Ongoing

A Randomized, Open-Label, Parallel Group Comparison of the Safety and Efficacy of Lovenox (Enoxaparin) Injection Vs. Adjusted Dose Coumadin (Warfarin) in the Prevention of Thromboembolic Disease Following Hip Replacement Surgery

Start date: 7 Nov 94	Estimated completion date:
Principal Investigator: Allan L. Bucknell, M.D.	Facility: BAMC
Department/Service: Surgery/Orthopedic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
 Total number of subjects enrolled to date: 18  
 Periodic review date: Nov of ea yr Review results: 18 patients

Objective(s): Twofold: (1) To evaluate the safety and efficacy of Lovenox Injection versus adjusted dose Coumadin in the prevention of clinically significant thromboembolic disease following elective total hip replacement during hospitalization. (2) To determine the medium term incidence (three months post-hospital discharge) of morbidity and mortality resulting from thromboembolic disease following elective total hip replacement surgery in patients treated with Lovenox Injection vs. adjusted dose Coumadin.

Technical Approach: Study plan, conduct of study, study medication, supplies and packaging, adverse events, etc. outlined in protocol.

Progress: Nov 95: We currently have 18 patients enrolled in the study, they are all completed with 3 patients being dropped from the study. We are currently enrolling in another study by the same drug company that has priority over this study until Dec 95. We have not enrolled any patients in this study since May 95 protocol remains open.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-10 Status: Completed

A Pilot Study of the Pharmacokinetics and Pharmacodynamics of Etomidate Administered by Inhalation

Start date: 24 Oct 94	Estimated completion date:
Principal Investigator: Paul Mongan, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Douglas M. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): 1. Describe the relationship between plasma etomidate levels and psychometric performance assessment using computer based testing.  
 2. Determine at what level of impairment subjects are aware of dysfunction.  
 3. Establish a model for testing the effects of anesthetic agents on psychometric performance. 4. Establish the pharmacokinetic and pharmacodynamic effects of etomidate administered by inhalation.

Technical Approach: Etomidate is a potent, short acting, non-barbiturate hypnotic which is commonly used for the induction of anesthesia by the intravenous route. However, novel methods of anesthetic delivery are desirable to meet the demands of unusual circumstances. Initial studies into the feasibility of inhalation uptake and distribution of etomidate have already been conducted. The development of an effective and safe inhalational method for the delivery of anesthetic agents could improve the clinical management of patients.

Progress: Oct 95: Completed data analysis in progress.

Side Effect: One subject experienced generalized urticaria and respiratory compromise within 2 hours of participating in one of the trials. Subsequent evaluation determined this was related to drug reaction related to antibiotic treatment for a dog bite temporarily related to participation in the study. Adverse reaction was not related to this study.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-11 Status: Ongoing

Effect of Nebulized Tetracaine on the Hemodynamic Response to Laryngoscopy and Tracheal Intubation

Start date: 28 Dec 94	Estimated completion date:
Principal Investigator: Patricia Vories, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): James B. Stevens, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
Total number of subjects enrolled to date: 30  
Periodic review date: Dec of ea yr Review results:

Objective(s): This study will involve the collection of data relating to changes in hemodynamics during laryngoscopy and tracheal intubation of patients with or without pretreatment with a nebulized local anesthetic. We will be comparing the effect of nebulized tetracaine vs placebo (saline) on changes in heart rate and systolic blood pressure in the minutes following laryngoscopy and intubation. Other local anesthetics, such as lidocaine and bupivacaine, have been studied in a similar fashion with some conflicting results. However, tetracaine has never been studied for this application. Tetracaine has been advocated as the local anesthetic of choice for topical anesthesia and this has been borne out clinically as well. We hypothesize that nebulized tetracaine administered prior to the induction of general anesthesia may blunt the hemodynamic response to laryngoscopy and intubation.

Technical Approach: This study will enroll thirty patients of both sexes who are of ASA physical status I or II who are scheduled for elective surgery which will require general anesthesia. Further specifics in protocol.

Progress: Dec 95: Study completed. No adverse effects encountered. Results indicated significant (p<.05) differences in heart rate with lower levels in the tetracaine group compared with placebo at intubation and the subsequent 5 minute intervals. Mean pressure was also significantly less at 1, 3, 4, 5 minutes after intubation. We conclude that tetracaine is well tolerated and may help attenuate hemodynamic response to intubation.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-12 Status: Completed

Use of Alpha-adrenergic Blocking Agents Compared to Anti-cholinergic Agents and Placebo in Women with Obstructive/Irritative Voiding Symptoms

Start date: 25 Dec 94	Estimated completion date:
Principal Investigator: Ian Thompson, M.D.	Facility: BAMC
Department/Service: Surgery/Urology	Associate Investigator(s): Paul A. Friedrichs, M.D., USAF Duane Cespedes, M.D., USAF Barbi Helfrick, RN Jean Johnson, PhD, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): 1. To compare the efficacy of an anti-cholinergic agent (oxybutynin), the current standard of therapy for obstructive/irritative voiding symptoms (OIVS) in women with the efficacy of an alpha-adrenergic agent (terazosin). 2. Compare the efficacy of these two agents with a placebo. 3. Determine if the American Urologic Assn Symptom Index is a valid tool for evaluating women who seek treatment for OIVS. 4. Pilot test procedures for enhancing medication-taking compliance in clinical trials.

Technical Approach: Medical application, status, technical approach, etc., outlined in protocol.

Progress: Dec 95: Study is completed as only one patient entered was eligible.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-15 Status: Ongoing

A Comparison of Aprotinin and Tranexamic Aid in Reducing Mediastinal Chest Tube Drainage and Allogenic Transfusions After Cardiopulmonary Bypass

Start date: 17 Jan 95	Estimated completion date:
Principal Investigator: Gregory Bouska, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Bryon McDonnell, M.D. R. Scott Brown, M.D. Brian K. Thwaites, M.D. Paul D. Mongan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether any difference exists in the ability of Aprotinin and Tranexamic Acid to decrease postoperative blood loss and transfusion therapy after cardiopulmonary bypass.

Technical Approach: Tranexamic acid is a primary antifibrinolytic agent that has been shown to decrease mediastinal blood loss and homologous blood tranfusion after CPB. Aprotinin is a nonspecific serine protease inhibitor that has also proven to be efficacious in blood onservation in numerous studies, although at a much greater cost than TA. Hence, TA may prove to be as efficacious while conserving costs.

Progress: No report available as of this date. Annual review due Jan 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-18 Status: Ongoing

Intraocular Silicone Oil in Surgery for Otherwise Inoperable Retinal Detachment

Start date: 23 Jan 95	Estimated completion date:
Principal Investigator: Wendall Bauman, M.D.	Facility: BAMC
Department/Service: Surgery/Ophthalmology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if silicone oil will be effective in the treatment of retinal detachment and restoring vision in eyes in which the retina cannot be reattached by conventional methods and the vision would otherwise be permanently decreased. The safety of silicone oil and its side effects are also to be evaluated.

Technical Approach: Subject selection, study design & procedures to be performed, managing adverse reaction, etc, are outlined in protocol.  
 Progress:

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-31 Status: Completed

An evaluation of pulse oximetry versus skin color in the assessment of patients in the post anesthetic unit

Start date: 1 Mar 95	Estimated completion date:
Principal Investigator: David C. Peters, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Richard B. Hecker, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): A prospective study designed to assess the use of pulse oximetry readings as a replacement for the Aldrete<sup>7a</sup> skin color score as a component of the patient discharge evaluation in the PACU.

Technical Approach: Pulse oximetry is a more accurate indicator of a patient's oxygenation status than skin color. All methods, assessments and procedures to be performed are currently accepted, approved, and routinely used. Based on this understanding, informed consent should not be required. Data could be collected retrospectively, but the study would be strengthened by prospective collection.

Progress: Although low PARS were not reported in our patient population, results suggest that the PARS scoring system is of limited value in assessing post-surgical patient due to the limitation of the skin color score in predicting  $S_pO_2$ . Within the past decade, non-invasive measurement of  $O_2$  saturation by pulse oximetry has become commonplace. Our results suggest that pulse oximetry measurements should be substituted for the skin color score in the PARS when assessing for the risk of post-surgical complications in the PACU.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-45 Status: Ongoing

The M-40A1 Protective Masks' Effect on Sleep: A Preliminary Study

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Sylvester G. Ramirez, M.D.	Facility: BAMC
Department/Service: Surgery/Otolaryngology Svc	Associate Investigator(s): Andrew Vories, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To conduct a preliminary study to observe physiologic changes resulting from the use of a M-40A1 Protective Mask (PM) during sleep. The purpose of the proposed study is to examine the physiologic consequences of using the PM during sleep, specifically we expect changes in sleep onset, time spent in Rapid eye Movement (REM) sleep, oxygen levels, hypopneas, and apneas.

Technical Approach: Subjects, exclusion criteria, materials/apparatus and specifics are outlined in protocol.

Progress: Oct 95: No actual work on this study has occurred. Awaiting funding from MRMC.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-68 Status: Ongoing

The Effect of a Peridex Rinsing Regimen on Wound Infection Rates in Major Head and Neck Surgery

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Luis Balbuena, M.D.	Facility: BAMC
Department/Service: Surgery/Otolaryngology Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To conduct a double blind randomized clinical trial to determine the effect of a perioperative oral rinsing regimen with chlorhexidine (Peridex) on the wound infection rate in major head and neck surgery.

Technical Approach: Hypothesis: Perioperative oral rinses w/Peridex will decrease the bacterial count of human saliva thereby decreasing the bacterial inoculum causing wound infections in patients undergoing major head and neck surgery. Materials/methods, statistical analysis, etc, are outlined in protocol.

Progress: No report available as of this date. Annual review due Dec 95.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-70 Status: Ongoing

## Racial Variation in Cephalometric Analysis

Start date: 30 Jan 95	Estimated completion date:
Principal Investigator: James J. Lee, M.D.	Facility: BAMC
Department/Service: Surgery/Otolaryngology Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate racial variations of mean values in cephalometric analysis. Specifically, one value will be investigated, PAS. This will be accomplished by comparing PAS value in six different groups: Caucasian Males, Caucasian Females, Black Males, Black Females, Hispanic Males and Hispanic Females.

Technical Approach: The hypothesis is that in cephalometric analysis, Posterior Airway Space do differ with racial and gender background.

Progress: No report available as of this date. Annual review due Jan 96.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-72 Status: Ongoing

Use of a Priming Dose of Vecuronium Prior to Rocuronium for Rapid Sequence Induction of Anesthesia

Start date: 17 Apr 95	Estimated completion date:
Principal Investigator: James B. Stevens, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Apr of ea yr Review results: \_\_\_\_\_

Objective(s): This study will collect data concerning the onset of and recovery from neuromuscular blockade. The investigators hypothesize that the addition of a small "priming" dose of vecuronium will speed onset of neuromuscular blockade when given three minutes prior to administration of a full dose of rocuronium.

Technical Approach: This study will utilize patients who are ASA physical status I, II, and III and who are scheduled for elective surgery requiring general anesthesia. exclusion criteria will include: patients with history of neuromuscular, hepatic, renal, or gastroesophageal reflux disease. Patients with abnormal airway anatomy and those taking medications known to interfere with neuromuscular transmission will also be excluded. No pregnant patients will be included in the study.

Progress: No report available as of this date. Annual review due Apr 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-82 Status: Ongoing

A Clinical Trial of Medical Therapy in Benign Prostatic Hyperplasia

Start date: 19 Dec 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: BAMC
Department/Service: Surgery/Urology Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): The primary objective of the NIH-BPH clinical trial is to ascertain if medical therapy (finasteride and/or doxazosin) delays or prevents the progression of BPH. The primary outcome ill be the time to clinical progression of BPH. Participants will be classified into one of four categories (outlined in protocol).

Technical Approach: Study design, eligibility criteria and detailed specifics are outlined in protocol.

Progress: Dec 95: Study is on hold awaiting official opening to accrual.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-83 Status: Ongoing

Determination of Normal Thromboelastogram (TEG) Parameters in Healthy Pregnant Women at Various Gestational Ages

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Tara L. Chronister, M.D.	Facility: BAMC
Department/Service: Surgery/Anesthesiology & Op	Associate Investigator(s): Kenneth Higby M.D. Reginald Singleton, M.D. David C. Peters, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the "normallL" thromboelastogram parameters obtained from healthy pregnant patients at different gestational ages.

Technical Approach: Hypotheses, technical validity of procedures, sample size, experimental design and specifics are outlined in protocol.

Progress: Investigator is currently on backfill away from BAMC. There is no report available as of this date.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-87 Status: Ongoing

## Sampling Error in Posttherapy Prostate Biopsy

Start date: 6 Mar 95	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: BAMC
Department/Service: Surgery/Urology	Associate Investigator(s): Thomas Rozanski, M.D. Leonard Renfer, M.D. Douglas Schow, M.D. Moo Cho, M.D. Renata Greenspan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): Determine the rate of false-negative sextant biopsy in patients with biopsy-proven prostate cancer.

Technical Approach: 100 consecutive patients who undergo radical prostatectomy will be studied. After the prostates are removed to be forwarded to the Department of Pathology, sextant biopsy of the prostate will be performed. Both the radical prostatectomy specimen and the prostate gland will thereafter be forwarded for pathologic processing.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-92 Status: Ongoing

The Effect of Epidural Volume on the Spread of Dermatomal Analgesia with Subarachnoid Hyperbaric Bupivacaine

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Catherine W. Cheung, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Gary D. Gridley, M.D. Douglas M. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): Determine the effect of epidural injection of different volumes of saline on the extent of sensory anesthesia after administration of subarachnoid hyperbaric bupivacaine.

Technical Approach: Medical application, status, study design and specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Mar 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-97 Status: Ongoing

A Double-Blind, Placebo-Controlled Clinical Trial Comparing the Efficacy and Safety of Prolonged Outpatient Enoxaparin and Placebo Therapies in the Prevention of Venous Thromboembolic Disease in Patients Undergoing Elective Primary Hip or Knee Replacement

Start date: 5 Jun 95	Estimated completion date:
Principal Investigator: Allan L. Bucknell, M.D.	Facility: BAMC
Department/Service: Surgery/Orthopedics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jun of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy and safety of a prolonged post-hospital regimen of enoxparin compared to placebo for the prevention of venous thromboembolic disease in the patients undergoing elective total hip or total knee replacement.

Technical Approach: Patient definition and other specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-109 Status: Ongoing

Biomarkers as Surrogate Endpoints in a Pilot Breast Cancer Chemoprevention Trial Using Tamoxifen

Start date: 2 Aug 95	Estimated completion date:
Principal Investigator: Ismail Jatoi, M.D.	Facility: BAMC
Department/Service: Surgery/Gen Surg	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): This study will include over 18 years of age female in- and out-patients. The investigational drug is Tamoxifen supplied by the Univ of Texas. We are entering a new era in breast cancer research in which testing of intentional therapies to prevent the disease will be a major focus. However, little is known about precursor lesions which may herald the eventual development of malignancy. Morphologic assessment identifies premalignant lesions with a higher risk of malignant progression, but this is insensitive. We hypothesize that certain biological markers which are abnormally expressed in malignant cells may also be abnormal in some premalignant lesions, which might indicate a greater risk of their evolving to cancer. Histological assessment of premalignant lesions an IHC assessment of biomarkers may provide surrogate endpoints for the initial evaluation of new preventive strategies. This project therefore represents a bold and reasonable new step to begin addressing these issues.

Technical Approach: Detailed specifics are outlined in protocol.

Progress: No report available as of this date. Annual report due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-112 Status: Ongoing

## Use of a Spring Loaded Device for Testicular Biopsy

Start date: 31 Jul 95	Estimated completion date:
Principal Investigator: Thomas Rozanski, M.D.	Facility: BAMC
Department/Service: Surgery/Urology	Associate Investigator(s): Ian Thompson, M.D. Doug Schow, M.D. Sridhar Natarajan, M.D. (Path) Moo Cho, M.D. (Path)
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3 as of 10/95  
Total number of subjects enrolled to date: 3  
Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if needle biopsy of the testis provides and adequate number of available tubules for definitive histologic interpretation.

Technical Approach: Patients going to the operating room for open testis biopsy or orchiectomy (other than for primary testis malignancy) would be counselled for participation in the study. After induction of anesthesia and prior to any surgical procedure, the Biopty gun (Bard Urological, Murray Hill, NJ) will be used to take two transcutaneous biopsies the testis. The specimens will be removed from the Biopty gun using a 26 gauge needle, placed in Bouin's solution, and sent to pathology labeled "Attention Dr. Wiener". Both needle specimens will be submitted together, and under low power magnification, the total number of available tubules will be determined, and a histologic diagnosis will be rendered based solely on the needle biopsy specimen. After needle biopsy, the definitive planned orchiectomy or open testis biopsy will be performed and the specimen processed in usual fashion for formal histologic evaluation.

Progress: 10/95: All 3 patients have undergone testicular needle biopsy without complications and additional operating room/anesthesia time is approximately 3 to 4 minutes. Correlation between needle biopsy and either open biopsy or orchiectomy specimen is very good, however, additional cases are required to complete the study.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-116 Status: Ongoing

## Intraocular Pressure Response to Nasal Steroids

Start date: 9 Aug 95	Estimated completion date:
Principal Investigator: John A. Campagna, M.D.	Facility: BAMC
Department/Service: Surgery/Ophthalmology	Associate Investigator(s): Benjamin Chacko, M.D. Ana A. Ortiz, M.D. David K. Hayes, M.D. Erin A. Doe, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): a. To determine the intraocular pressure (IOP) response to nasal steroids. b. To determine if there are any risk factors for the development of an increased IOP with nasal steroids i.e. Diabetes Mellitus, myopia, or family history of glaucoma.

Technical Approach: Prospective, controlled, randomized, single linded study comparing IOP response in patients on nasal steroids (Beclomethasone) vs IOP response i patients receiving a nonsteroidal agent (Cromolyn sodium) for the teatment of allergic rhinitis. Sample size will be 116 patients.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-119 Status: Ongoing

A Direct Comparison of Two Methods for Determining Cardiac Output and Pulmonary Artery Pressure in the Operating room: Transesophageal Echocardiography and Pulmonary Artery Catheterization

Start date: 11 Sep 95	Estimated completion date:
Principal Investigator: Robert Oldroyd, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Brian K. Thwaites, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether TEE can accurately estimate cardiac output and pulmonary artery pressure in the majority of patients undergoing coronary artery bypass surgery when these estimations are compared to those obtained by PAC.

Technical Approach: The hypothesis is that TEE will be able to generate accurate cardiac output and pulmonary artery pressure estimations in a large percentage of patients undergoing cardiac surgery when compared to those values obtained by PAC. Further specifics in protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-123 Status: Ongoing

Comparative Study of the Clinical Efficacy of Two Dosing Regimens of EULEXIN

Start date: 14 Aug 95	Estimated completion date:
Principal Investigator: Thomas Rozanski, M.D.	Facility: BAMC
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the clinical effectiveness of a new dosing regimen (500 mg QD) for administering flutamide to the currently indicated dosing regimen of 250 mg Q8H according to: Percent of patients normalizing PSA; Secondly, Quality of Life differences between the two regimens will be measured.

Technical Approach: Multi-center, open label, prospective randomization. Further specifics are in protocol.

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-133 Status: Ongoing

A Research Study to Determine the Effect of Punctal Occlusion on Intraocular Pressure in Patients Taking Topical Glaucoma Therapy

Start date: 8 Sep 95	Estimated completion date:
Principal Investigator: Edward F. Leuschner, M.D.	Facility: BAMC
Department/Service: Surgery/Ophthalmology Svc	Associate Investigator(s): Benjamin Chacko, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if with complete punctal occlusion and with the glaucoma medication contained in the tear lake for a longer period of time, there is a clinically measurable and beneficial result: the lowering of intraocular pressure.

Technical Approach: Intend to prove whether or not the clinical outcome of successful therapy for glaucoma is affected by punctal occlusion with silicone plugs. The test patients will have bilateral glaucoma and dry eye. The patients will be on monotherapy with a beta blocker. The alternative hypothesis is that there will be a decrease in the IOP in the treated eye.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-137 Status: Ongoing

Subanesthetic Propofol Infusion for Prophylaxis Against Emesis in Laparoscopic Day Surgery

Start date: Oct 95	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Christopher J. Duggins, M.D. Douglas M. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if a low dose propofol infusion decreases the incidence of postoperative emetic sequelae after laparoscopic surgery. Null hypothesis: No changes in incidence of postoperative emesis occur after propofol infusion.

Technical Approach: Hypothesis to be tested, sample size, description of subjects, exclusion criteria, etc., are outlined in protocol.

Progress: No report available as of this date. Annual review due Oct 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-138 Status: Ongoing

A Comparison of Prophylactic Ondansetron and Droperidol for Strabismus Repair in Adults

Start date: 16 Oct 95	Estimated completion date:
Principal Investigator: Perry E. Jones, M.D.	Facility: BAMC
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Erin Doe, M.D. R. Scott Brown, M.D. Mary O'Hara, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): To determine whether any difference exists between ondansetron and droperidol in the relief of nausea and vomiting in adults undergoing strabismus surgery.

Technical Approach: Null hypothesis, sample size, study design, study population, methods, etc., are outlined in protocol.

Progress: No report available as of this date. Annual review due Oct 96.

# Detail Summary Sheet

Date: 1 Dec 95      Protocol Number: C-95-140      Status: Ongoing

Results of Transurethral Incision/Resection of the Prostate in Men Treated Medically for Benign Prostatic Hyperplasia

Start date: Aug 95	Estimated completion date:
Principal Investigator: Douglas Schow, M.D.	Facility: BAMC
Department/Service: Surgery/Urology Svc	Associate Investigator(s): Ian M. Thompson, .D. Thomas Rozanski, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the degree of improvement following surgical therapy for BPH in men receiving medical therapy for symptoms of prostatism. To characterize those men who elect surgical therapy following medical therapy for prostatism.

Technical Approach: Specific details are outlined in protocol

Progress: No report available as of this date. Annual review due Aug 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-142 Status: Ongoing

Hemodynamic Effects of Rocuronium Compared to Vecuronium

Start date: 13 Jul 95	Estimated completion date:
Principal Investigator: James B. Stevens, MD	Facility: BAMC
Department/Service: Surgery/Anes & Op	Associate Investigator(s): Richard B. Hecker, MD Steven Walker, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the relative hemodynamic effects of 2-4 x ED95 rocuronium compared to 2 x ED95 vecuronium used during normal maintenance of anesthesia.

Technical Approach: Study will enroll patients who are ASA Physical Status I, II, and III aged 18-65 who are scheduled for elective surgery requiring general anesthesia. Exclusion criteria will include history of coronary artery, hepatic, renal, or neuromuscular disease. Patients taking anti-hypertensive drugs or drugs that interfere with neuromuscular transmission will be excluded. No pregnant patients will be included in the investigation. Further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Jul 96.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-16 Status: Ongoing

Title: Comparison of Four Treatment Approaches for Adhesive Capsulitis of the Shoulder

Start date: 14 Dec 92	Estimated completion date:
Principal Investigator: Gail Deyle	Facility: Brooke Army Medical Center, Texas
Department/Service: Phys Med/Physical Therapy	Associate Investigator(s): John Halle Jean Bryan
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Dec of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of routine conservative treatments on adhesive capsulitis of the shoulder. Four treatment approaches will be contrasted, with results based on objective measures of passive range of motion and pain assessment as measured with a visual analog scale.

Technical Approach: Investigation of the response of shoulders with adhesive capsulitis will be examined over a 24 month treatment period. Effectiveness will be assessed over time and summarized both for the short term response (under six months), and for the long term outcome (from six months to two years). The dependent variables assessed will be passive shoulder range of motion, and pain as assessed with a visual analog scale. Visual analog scales have been validated as ratio scale measures for both chronic and experimental pain. Range of motion will be assessed on the involved shoulder for flexion, extension, abduction, internal and external rotation. Further specifics in protocol.

Progress: Study has been placed on hold status pending reassignment of this project to another principal investigator.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-109 Status: Completed

Title: Phonophoretic Delivery of 10% Hydrocortisone Through the Epidermis as Determined by Blood Cortisol Concentrations

Start date: Aug 93	Estimated completion date:
Principal Investigator: Anthony C. Bare	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Allyson E. Pritchard Maire B. McAnaw Jeffrey G. Struebing
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 24  
Total number of subjects enrolled to date: 24  
Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if phonophoresis transcutaneously delivers topically applied hydrocortisone cream in healthy humans. An aquasonic gel coupling agent containing 10% hydrocortisone will be used during a standard (clinical) ultrasound treatment to determine if the medication is delivered through the skin. Serum cortisol levels before, during and after treatment will be compared to one other control treatment in a 2 x 2 within subjects ANOVA.

Technical Approach: Subjects, exclusion, experimental design, procedures, data collection and specifics outlined in protocol.

Progress: No adverse incidents.

Aug 95: The findings suggested that was no penetration of hydrocortisone through the epidermis of humans as detected in the underlying vasculature. Use of 10% hydrocortisone phonophoresis, as it is applied in current clinical practice, is questioned. Clinical implications are presented and further research is suggested.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-111 Status: Completed

Title: Spinal Mobilization in Entry Level Physical Therapy Curricula

Start date: Aug 93	Estimated completion date:
Principal Investigator: D. Lyle McClune, ENS MSC USN	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Susan Romito
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): 1) How are entry level physical therapy programs meeting the new 1992 "competency in mobilization" requirement established by the American Physical Therapy Association (APTA)? 2) What quantitative changes have occurred in spinal mobilization entry level curricula from 1986-1993?

Technical Approach: The purpose of this study is to determine what effect the "competency in mobilization" requirement, established by the APTA, has had on the instruction of spinal mobilization in entry level physical therapy programs. This descriptive study will provide specific information on spinal mobilization education. The information will be collected by way of a mail survey. Further specifics in protocol.

Progress: The investigator did not provide an annual/final report prior to reassignment.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-113 Status: Ongoing

Title: A Comparison of Two Physical Therapy Treatment Approaches to Shoulder Impingement: Rotator Cuff Exercise Program and Rotator Cuff Exercise with Manual Physical Therapy

Start date: 6 Jul 94	Estimated completion date:
Principal Investigator: Gail Deyle, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s):
Key Words: impingement, rotator cuff	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 18  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of two commonly used physical therapy approaches in the treatment of impingement syndrome of the shoulder.

Technical Approach: This study not only provides important information regarding the most effective conservative treatment of this very common physical ailment but also provides a test of the intricate relationship between the cervical spine and shoulder pain.

Progress: Physical therapy has been instructed and supplied with patient screening forms to determine appropriate candidates. October.

Randomized booklet prepared sequentially for each patient with all forms, handouts and procedural checklist. Group assignment coded in booklet to keep tester blinded.

Jul 95: No complications; 18 patients enrolled to date. Research is encouraging. Plan to continue taking data.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-116 Status: Completed

Title: Oxygen Consumption in Women During Backward Walking at Different Speeds

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Erica Clarkson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Patricia McCracken Christi Trimble Shelley Cameron
Key Words: Backward walking, oxygen consumption	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 25  
 Periodic review date: Review results:

Objective(s): What is the relationship between oxygen consumption and backward walking speeds (2.0, 2.5, 3.0, 3.5, and 4.0 miles per hour) in healthy women? This will be a descriptive study. The independent variable is backward walking speed and the dependent variables are oxygen uptake and heart rate. No medications will be used. Subject population: Normal, healthy, adult female volunteers.

Technical Approach: Description of subjects, methods and details are outlined in protocol.

Progress: No adverse incidents.

Aug 95: Twenty-five healthy, adult female volunteers participated in this study. Subjects were tested at speeds of 0.96, 1.20, 1.43, 1.67 and 1.91 meters per second. Subjects also performed a graded exercise stress test. analysis revealed curvilinear relationships between oxygen consumption and speed and heart rate and speed. With these results clinicians may now prescribe specific speeds of bckward walking for women to elicit a desired cardiopulmonary response.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-117 Status: Completed

Title: The Effects of Tai Chi on Functional Reach in Healthy Adults over 50

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Janenne Ellis, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Amy Eschenberg Tom Schroeder Amy Trevino
Key Words: Tai Chi, Sham, control	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 28  
Total number of subjects enrolled to date: 28  
Periodic review date: Review results:

Objective(s): Does a six week instructional program in tai chi improve functional reach in a healthy individual over 50 years of age? This study is a two-factor mixed design with repeated measures on one factor. The between-subjects factor is group, and has three levels: Tai Chi, Sham, and Control. The repeated factor is time, and the levels are Pre and Post. The dependent variable is functional reach. The Table of Random Numbers will be used to assign groups from a volunteer subject population of healthy, neurologically intact DOD beneficiaries.

Technical Approach: Description of subjects/controls, experimental design and methods are outlined in protocol.

Progress: Research is ongoing. Tai Chi instructional group is beginning its first session.

Jul 95: Research has been completed. Sixty-two subjects were invited for the study. No problems arose during the study and all subjects completed the study without injury. We are currently in the process of submitting our article to the Journal of Gerontology.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-118 Status: Completed

Title: Effect of Joint Angle on Accuracy and Reliability of Hand-Held Dynamometer Measurements of Quadriceps Isometric Force

Start date: 19 Jul 94	Estimated completion date: Feb 95
Principal Investigator: Christine Held, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Laura Collins Laura Vitcenda Manuel Domenech Stephen C. Allison Howard Rice
Key Words: quadriceps, isometric, isokinetic, dynamometer	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 30  
Total number of subjects enrolled to date: 30  
Periodic review date: Review results:

Objective(s): The purpose of this research is to examine the effect of four knee angles on the accuracy and reliability of quadriceps isometric force measurements taken with a hand-held dynamometer as compared to those taken with an isokinetic dynamometer.

Technical Approach: When compared to isokinetic dynamometer measurements, accurate and reliable peak quadriceps force values can be obtained at 30, 60, 90 and 120 degrees of knee flexion utilizing HHD and standard prone test position. Procedure, subjects, instrumentation, data collection and statistical analysis are outlined in protocol.

Progress: Collected data on 22 subjects thus far, and plan to be finished with data collection by 31 Oct 94. No problems or adverse reactions with the subjects thus far.

Jul 95: Research project is completed. Collected data on 26 subjects. No problems were encountered.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-120 Status: Completed

Title: The Immediate Effect of Upper Extremity Resistive Exercise on Upper Extremity Motor Performance in Subjects with Hemiparesis

Start date: 19 Jul 94	Estimated completion date: Feb '95
Principal Investigator: Frank P. Pearson, MS, USN	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Timothy L. Pendergrass Deydre Smyth Thomas Longhway
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Rsch Question: Does upper extremity resistive exercise of the paretic limb in subjects with hemiplegia after performance of the same limb on the Box and Block Test immediately after the exercise?

Technical Approach: Hypothesis: Upper extremity resistive exercise will not produce detrimental effects on upper extremity motor performance in subjects with hemiparesis. Subject criteria, design/methods and specifics are outlined in protocol.

Progress: Subject recruiting in progress. Data collection target date 27 Aug 94.

Jul 95: This is a final report. The study is complete. Abstract has been submitted.



# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-121 Status: Completed

Title: Investigation of the Validity and Reliability of Five Objective Techniques for Assessing Forward Shoulder Posture

Start date: 19 Jul 94	Estimated completion date: Feb 95
Principal Investigator: Debra E. Peterson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy AMEDDC&S	Associate Investigator(s): Kenneth Blankenship Joel B. Robb Michael Walker Lynne Mincey Jean Bryan Gary Simmons Deborah Stetts
Key Words: scapular, musculoskeletal, dysfunction, spine, cervical, thoracic, shoulder girdle, scoliosis, kyphosis	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 50  
Total number of subjects enrolled to date: 50  
Periodic review date: Review results:

Objective(s): What are the reliability and validity of five different clinical methods (Baylor Square, Radiograph Calipers, Sahrman Technique, Measure of scapular position, and Double Square) of assessing forward shoulder posture? Study design: Correlational. Study population: Fifty adults, ages 18-50 with no history of activity limiting musculoskeletal pain; dysfunction of the spine; or cervical, thoracic, or shoulder girdle fractures or anomalies. Subjects will also have no apparent scoliosis or abnormal thoracic kyphosis on visual exam. Pregnant subjects will be excluded from the study. Twenty-five or more subjects will have an assessment of forward shoulder posture.

Technical Approach: Subjects are assessed for apparent scoliosis or abnormal thoracic kyphosis, and then the subject is identified as either having or not having forward shoulder posture. A lateral c-spine radiograph is performed and shoulder posture measurements are taken using the above mentioned tools or methods. Hypothesis, subjects, physical exam and methods are outlined in protocol.

Progress: The measurement using the radiographic calipers was deleted from the study because the available radiographic calipers were deemed unreliable. Data collection on all 50 subjects has been completed with no adverse reactions.

Jul 95: Study has been completed and abstract submitted.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-132 Status: Ongoing

Title: Normative Data for the Timed Functional Movements Test

Start date:	Estimated completion date:
Principal Investigator: Jane E. Freund, MS, PT	Facility: Brooke Army Medical Center, Texas
Department/Service: Phys Ther/AMEDDC&S	Associate Investigator(s): Patricia Sargeant, MPT, Wilford Hall
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jul of ea yr Review results:

Objective(s): To determine normative values for Timed Functional Movements in an older adult population.

Technical Approach: Study design, test description, medications used, medical application and further details outlined in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

Jul 95: Due to unforeseen workload my first year on faculty of the US Army-Baylor University Graduate Program in Physical Therapy, I have been unable to begin data collection. There has been no change in the protocol or primary investigator. Requesting completion date be extended to Jul 96.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-138 Status: Completed

Title: Investigation of Inter-Rater Reliability of Five Objective Techniques for Assessing Forward Shoulder Posture

Start date: 8 Sep 94	Estimated completion date:
Principal Investigator: Jean M. Bryan	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Lynne M. Mincey Deborah M. Stetts Debra E. Peterson Kenneth R. Blankenship Joel B. Robb
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
Total number of subjects enrolled to date: 10  
Periodic review date: Sep of ea yr Review results: See below

Objective(s): Rsch question: What is the inter-rater reliability of five different clinical methods (Baylor Square, Radiograph Calipers, Sahrman Technique, Scapular position, and Double Square) of assessing forward shoulder posture. Study design: Correlational Medications used: none

Technical Approach: The five methods are reliable between raters for assessment of forward shoulder posture. There will be two groups of "subjects" who will need to sign volunteer consent forms for this research. One group is the physical therapists who will assess inter-rater reliability; the second group are the subjects the therapists will be measuring. Further details outlined in protocol.

Progress: Aug 95: Only 4 measures were taken: Baylor Square, Tape Measure, Wall Slide and double square. Radiographic Calipers were not measured due to problems with the equipment. Ten subjects were measured by 15 therapists. Per the protocol, the patient/subject agreement forms are on file with Clinical Investigation. We were not required to obtain consent forms from the therapists/practitioners for their participation. The research followed the prescribed protocol with experienced physical therapists assessing forward shoulder posture of the inter-rater reliability for each assessment technique. The ICC was .85 for the Baylor square, .69 for the Sahrman technique, .73 for the tape measure, and .15 for the double square. These findings were fairly consistent with a previous study assessing the inter-rate reliability of these techniques. Overall the Baylor Square appears to have he higher inter-rater reliability. This higher reliability is most probably due to the free standing position (subjects were not standing against the wall) of this technique. When subjects did not receive proprioceptive feedback from the wall, their posture may have been more consistent between trials. Further research and perfection of the Baylor Square are indicated.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-138 Status: Ongoing

Title: Use of an Anti-Spasmodic Medication (Dicyclomine) Prior to Flexible Sigmoidoscopy

Start date: Nov 94	Estimated completion date: Dec 95
Principal Investigator: John D. Cowsar, D.O.	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physicians Assistant Br, AMEDDC&S	Associate Investigator(s): Charles E. Henley, D.O.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Nov of ea yr Review results:

Objective(s): To demonstrate that the pre-administration of dicyclomine prior to flexible sigmoidoscopy can reduce patient discomfort due to bowel spasm during the procedure. The hypothesis is that the anticholinergic, dicyclomine, is significantly more efficacious than placebo in reducing pain during flexible sigmoidoscopy. Another objective of this study is to measure the pressure of air administered through the sigmoidoscope to insufflate the bowel lumen and attempt to correlate these air pressure measurements with degree of patient discomfort and depth of instrument insertion achieved by the operator. The study population which will be observed is comprised of adult women who have flexible sigmoidoscopies performed in the gastrointestinal clinic at Brooke Army Medical Center.

Technical Approach: The hypothesis of this clinical study is that dicyclomine is significantly more efficacious than placebo in reducing discomfort due to bowel spasm, thus allowing a greater depth of scope insertion than placebo during flexible sigmoidoscopy.

Progress: We plan to start this study in November 1994.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-92-7 Status: Ongoing

Title: Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of Acute Urticaria Over a Seventy-Two Hour Period

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: CPT Anthony Ferrara, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Cimetidine Urticaria Ranitidine Diphenhydramine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 18

Periodic review date: Feb of ea yr Review results:

Objective(s): To determine the effectiveness of cimetidine, ranitidine and diphenhydramine in the treatment of acute urticaria during the immediate ER follow-up period.

Technical Approach: Subjects in this study will include 120 male and female patients between the ages of 16 and 55 presenting to the Emergency Room at Darnall Army Community Hospital with signs and symptoms consistent with acute urticaria of less than 24 hour duration. Presenting symptoms should include itching, swelling, and rash.

Progress: Study still ongoing for patient enrollement.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-93-128 Status: Ongoing

Title: A Prospective Randomized Double-Blinded Evaluation of Prochlorperazine versus Sumatriptan for the Emergency Department Treatment of Migraine Headache

Start date: 16 Aug 93	Estimated completion date:
Principal Investigator: Kevin Hammond, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): David B. Cline, M.D. Margaret J. Karnes, D.O. Donald M. Yealy, M.D. Marco Coppola, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of prochlorperazine versus sumatriptan for the emergency department treatment of migraine headache.

Technical Approach: Patients between the ages of 18 and 60 who present to our Emergency departments with a migraine headache as defined by the Ad Hoc Committee on Classification of Headache will be entered into the study. Patients with certain conditions outlined in protocol will be excluded.

Progress: Still collecting data.  
Aug 95: No input furnished.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-29 Status: Ongoing

Title: Assessment of Risk Factors for HIV Infection Among Active Duty US Military Personnel with Documented Recent HIV-Antibody Seroconversion - Phase II

Start date:	Estimated completion date:
Principal Investigator: Carrie M. Carson, RN	Facility: DAH & Brooke Army Medical Center, Texas
Department/Service: PVNTMED Epidemiology & Disease Control	Associate Investigator(s):
Key Words: seroconversion	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): To evaluate biologic and behavioral determinants of HIV seroconversion by comparing medical, demographic, and behavioral histories of active duty personnel recently infected with HIV to histories of individuals who have not seroconverted over a similar time period.

Technical Approach: Eleven Army installations within the continental US will be selected based upon the presence of active duty soldiers with documented seroconversion from HIV-Ab negative to HIV-Ab positive. In 1992, approximately 70% of new incident cases in the Army were identified at these installations. The feasibility of conducting the study at sites in both the Navy and Air Force is currently being evaluated.

Progress: Addendum submitted for recommended changes to the agreement affidavit. Start date projected for Oct 94.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-35 Status: Ongoing

Title: HOOD Evaluation of Albuterol Metered Dose Inhaler Effects on Serum Potassium Levels in Healthy Adults: A Prospective Study

Start date: 28 Jan 94	Estimated completion date:
Principal Investigator: Robert T. Gerhardt, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Emerg Medicine, DAH	Associate Investigator(s): Ronald Brace, M.D. Marco Coppola, D.O.
Key Words: Albuterol, Metered Dose Inhaler (MDI)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jan of ea yr Review results: \_\_\_\_\_

Objective(s): This study is designed to determine whether the inhalation of albuterol from a portable, metered-dose inhaler (MDI) system causes clinically significant decreases in serum potassium levels in normal, healthy adults; and further, to quantify the extent and duration of such a decrease.

Technical Approach: Healthy male and female adult volunteers aged 18 to 50 will be recruited for participation. It is estimated that a total of 24 subjects (eight per experimental group) will be needed to obtain significance under this study's design (see Design & Methods in protocol).

Progress: Waiting for drug company to come through with placebo.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-40 Status: Ongoing

Title: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Versus TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

Start date: 28 Jan 94	Estimated completion date:
Principal Investigator: Timothy J. Kietzman, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Ophthalmology, DAH	Associate Investigator(s): John T. McDonnold, II, M.D. Reginald H. Moore, M.D. Mark S. Foster, M.D.
Key Words: Ciprofloxacin, TOBREX, conjunctivitis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jan of ea yr Review results:

Objective(s): The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivitis. Acute is defined as having a duration of one week or less.

Technical approach: Materials/methods, subjects, study procedure, etc. outlined in protocol.

Progress: No patients were enrolled in the program because medication was never received from the drug company.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-55 Status: Ongoing

Title: A Single-Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

Start date: 7 Feb 94	Estimated completion date: Jul 95
Principal Investigator: Tracy L. Biediger, M.D.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology Service	Associate Investigator(s):
Key Words: Retin-A 0.05% Cream, comedonal acne vulgaris,	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 28  
 Total number of subjects enrolled to date: 28  
 Periodic review date: Feb of ea yr Review results:

Objective(s): To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads/whiteheads) acne vulgaris.

Technical Approach: Approximately 60 patients with comedonal acne vulgaris will be randomized to a treatment method involving either once nightly, once every other night, or once weekly application of tretinoin (Retin-A) 0.05% cream to the affected areas. To be eligible for the study, patients must not have received other treatment for their acne during the preceding 2 months. Pregnant or nursing females and females who have commenced or stopped oral contraceptives during the preceding 90 days will be excluded from the study. Treatment will be continued for a total of 3 months. Followup exams will be conducted at 4, 8 and 12 weeks.

Progress: Recruitment of patients has been very slow.

As of July 1994, Tracy L. Biediger, M.D., has been assigned as staff dermatologist at Darnall ACH, Fort Hood, TX, and will therefore serve as Principal Investigator at this facility. Leo Conger, M.D., will serve as PI for the study at BAMC.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-58 Status: Ongoing

Title: A Double Blind Evaluation of Ketorolac Tromethamine and Butorphanol Tartrate for the Emergency Department Management of Ureteral Colic

Start date: 25 Feb 94	Estimated completion date:
Principal Investigator: Daniel T. Ching, D.O.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): Michael E. Mullins, M.D. Marco Coppola, D.O. Margaret J. Karnes, D.O. Donald M. Yealy, M.D.
Key Words: Ketorolac Tromethamine, Butorphanol Tartrate, Ureteral Colic	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 14

Total number of subjects enrolled to date: 14

Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of ketorolac tromethamine (KT) and butorphanol tartrate (B) for the Emergency Department management of ureteral colic.

Technical Approach: All patients between the ages of 18 and 65 presenting with symptoms consistent with renal colic will be eligible for this study. Patients must also demonstrate urine dipstick hematuria. Exclusion criteria outlined in protocol. Monitoring of pain, vital signs and other specific data also outlined in protocol.

Progress: Data being collected.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-98 Status: Ongoing

Title: A Double-Blinded, Randomized Comparison of Viscous Lidocaine Gel for Topical Anesthesia of Dermal Lacerations in Adults

Start date: 4 May 94	Estimated completion date:
Principal Investigator: Marco Coppola, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH	Associate Investigator(s):
Key Words: Lidocaine Gel, viscous cocaine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: May of ea yr Review results: \_\_\_\_\_

Objective(s): To compare a new formulation of viscous cocaine and lidocaine gel for topical anesthesia in the management of dermal lacerations.

Technical Approach: The null hypothesis is that no difference exists between viscous cocaine and lidocaine gel in anesthetic effect for dermal lacerations. The subjects for this trial will consist of 60 adults between the ages of 18 and 40, who present to the Emergency Department of Darnall Army Community Hospital within 6 hours of obtaining a simple dermal laceration. The individual must be in good health without any history or evidence of chronic disease.

Progress: No patients have been entered because of problem with preparing study medication.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-102 Status: Ongoing

Title: A Radiographic and Functional Analysis of Short Arm Cast vs Volar Splint Immobilization in Preventing Angulation of Small Finger Metacarpal Neck Fractures

Start date: 1 Jun 94	Estimated completion date: Jun 95
Principal Investigator: Jon A. Garramone, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Orthopedic Surgery Svc, DACH	Associate Investigator(s): Dustin Frazier, M.D. Keith Moore, M.D. Cassandra Lewis Darryl Peterson, M.D. Paul Spezia, D.O.
Key Words:	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 37  
Total number of subjects enrolled to date: 37  
Periodic review date: Jun of ea yr Review results:

Objective(s): We will prospectively evaluate all isolated closed small finger metacarpal neck fractures seen at DACH for loss of anatomic position or reduction during immobilization. We will also compare the effectiveness of cast vs. volar splint immobilization and evaluate hand function following treatment of this fracture using immobilization.

Technical Approach: All isolated closed small finger metacarpal neck fractures in patients 18 years of age or older seen by the Orthopedic Surgery Service at DACH will be examined (both physically and radiographically) and treated within one week of the initial injury. Each fracture will be evaluated for pain, tenderness, deformity, neurovascular damage, and hand/finger range of motion. The age and sex of the patient, dominant vs non-dominant hand involvement, patient occupation, and mechanism of injury will also be obtained. Further details included in protocol.

Progress: As of 12 Sep 94, 13 of the 22 subjects have completed the study protocol. Of the 22 subjects, 12 have been placed in a volar splint while the additional 10 have used a cast for immoiliation. All patients have been evaluated per the study protocol, and there has been no complication to date. May 95: Study ongoing; data will be analyzed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-104 Status: Completed

Title: Influence of Needle Orifice Direction During Injection on the Distribution of Hyperbaric 0.75% Bupivacaine within the Subarachnoid Space using a 25 Gauge Whitacre Spinal Needle

Start date: 20 Jun 94	Estimated completion date: Aug 95
Principal Investigator: Franklin McShane, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing Dept, DAH	Associate Investigator(s): Christie Wieczorek, AN Michael Kapp, AN Nelson Burgos, AN
Key Words: Bupivacaine, Whitacre spinal needle, subarachnoid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Jun of ea yr Review results: None

Objective(s): This study will answer the following research question: Will the direction of the needle orifice during injection of anesthetic into the subarachnoid space, using a Whitacre spinal needle, affect the distribution achieved?

Technical Approach: The purpose of this study is to assess the effect of needle orifice direction on distribution of local anesthetic within the subarachnoid space using a 25G Whitacre spinal needle. The Whitacre spinal needle is different from conventional spinal needles in that its orifice does not lie in the same plane as the shaft of the needle. Rather it opens perpendicular to the shaft and two millimeters proximal to the distal tip of the needle. This allows for different directions of injection. If a significant difference in height of block exists based on needle orifice direction then the anesthetist will be able to deliver anesthesia with greater predictability. Further details outlined in protocol.

Progress: Data collection is completed. Statistics and conclusion being developed.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-111 Status: Completed

Title: A Multi-Center, Prospective Study of the Microbiology of Infected Dog and Cat Bite Wounds

Start date: 29 Jun 94	Estimated completion date:
Principal Investigator: Marco Coppola, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emerg Med, DAH	Associate Investigator(s): John T. McDonnold, D.O.
Key Words: empirically	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jun of ea yr Review results:

Objective(s): Purpose of this study is to define and characterize the microbiology of infected cat and dog bite wounds. In addition, the various therapies utilized to empirically treat these infections will be tabulated and a correlation determined, if any, between the success or failure of therapies and the antibiotic susceptibility of infecting organisms.

Technical Approach: This study will be conducted at 18-20 study sites. The initial list of study sites and co-investigators is provided in protocol. Each investigator is a faculty member of an academic emergency medicine training program. Therefore, cases can be enrolled 24 hours per day, seven days per week through emergency department surveillance. The study will continue until a total of 100 evaluable patients with dog bite infections and 50 evaluable patients with cat bite infections have completed the study protocol.

Progress: Data being collected. Completed at Darnall ACH (Apr95).

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-115 Status: Ongoing

Title: A Study of Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

Start date: 7 Jul 94	Estimated completion date:
Principal Investigator: Gary Gridley, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Anes & Op Svc, DAH	Associate Investigator(s): Christina L. Szigeti, M.D.
Key Words: paramedian, midline, headj- ache, Quincke and Whitacre Spinal needles	Douglas M. Anderson, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

Technical Approach: Hypothesize: 1. The paramedian approach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle; 2. The paramedian approach using the quincke needle is associated with less PDPH than the midline Quincke method; 3. The paramedian approach using the Quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Further details outlined in protocol.

Progress: Awaiting new OB physicians at DAH to evaluate study.  
 Jul 95: Arranging for new PI at DACH; notice forthcoming.



# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-122 Status: Completed

Title: A Comparison of Initial Success Rates for Student Registered Nurse Anesthetists Performing Oral Endotracheal Intubation with the Miller Blade Versus the Macintosh Blade

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Barry Thibodeaux	Facility: Brooke Army Medical Center, Texas
Department/Service: DAH - US Army/UTHSC Houston Anes Nurs	Associate Investigator(s): Michael Fitzgibbon FAMC Deborah Selber Barry Vance
Key Words: Endotracheal intubation, Miller Blade, Macintosh Blade	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Jul of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if there is a difference in success rates for the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade versus the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade versus the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Macintosh blade.

Technical Approach: Synopsis, study design, medication used, type of subject population observed and number are all outlined in protocol.

Progress: Jul 95: Study is complete. Data showed no significant difference between success rates for students who intubated using a Miller Blade versus a Macintosh blade. The research question tested at  $p = .07$  for the first 25 patients intubated per student. However, a plot of the raw data revealed the steepest part of the learning curve occurred with the first ten patients intubated per student. The difference between success rates for the first ten patients per student was significant at  $p = .03$  level. Awaiting approval from UT-Houston Health Science center concerning our thesis.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-128 Status: Ongoing

Title: Smoking Behavior, Knowledge, and Attitudes of Pregnant Women in a Military Health Care Setting: Difference among Races, Ethnic Groups, and Military Ranks

Start date:	Estimated completion date:
Principal Investigator: Wanda T. Planadeball, Nurse	Facility: DACH Brooke Army Medical Center, Texas
Department/Service: OB/Gyn, Darnall ACH	Associate Investigator(s): Leocadio Melendez-Figueroa Debra Brown
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): To describe the prevalence of smoking, attitudes, and smoking health knowledge among pregnant women serviced in a military health care setting. To describe differences among races and ethnic groups, military ranks, income and education. To describe differences between infant birth-weight of pregnant women who smoke against infant birth-weight of pregnant women who do not smoke serviced in military health care setting.

Technical Approach: This is a cross-sectional correlational study designed to: 1. Estimate the prevalence of smoking of pregnant women across different social demographic variables; 2. Correlate the health beliefs, knowledge, and attitudes of pregnant women eighteen years of age and older with their intentions to smoke, smoking habits and infant birth weight.

Progress: This is a new study. There is no reportable data.  
 Aug 95: The first phase of the study (Pilot Study) has been completed.  
 Preliminary Findings are on file in DCI.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-141 Status: Ongoing

Title: Analgesia for Reduction of Acute Glenohumeral Dislocation: Intra-articular Lidocaine Versus Intravenous Fentanyl

Start date: 14 Sep 94	Estimated completion date:
Principal Investigator: Marco Coppola, D.O.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: DACH Emergency Medicine	Associate Investigator(s): Victor Gennaro, D.O.
Key Words:	Original PI Joseph Hoffman, M.D. has PCS'd
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
 Total number of subjects enrolled to date: 19  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): To contrast the analgesic efficacy of intra-articular lidocaine versus intravenous fentanyl in an adult population suffering from acute glenohumeral dislocation.

Technical Approach: Hypothesize that intra-articular lidocaine is just as an efficacious analgesic for the reduction of acute glenohumeral dislocations as intravenous fentanyl.

Progress: Aug 95: Study ongoing.

# Detail Summary Sheet

Date: Dec 95 Protocol Number: C-94-144 Status: Ongoing

Title: Neuropsychological Impairments Associated with Antisocial Personality and Alcoholism

Start date: 20 Sep 94	Estimated completion date:
Principal Investigator: Helene Barrette CPT Psychologist	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: DACH Psychology Dept	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25-27  
Total number of subjects enrolled to date: 25-27  
Periodic review date: Sep of ea yr Review results: Ongoing

Objective(s): Twofold: 1. To assess whether neuropsychological functions can discriminate individuals with primary alcoholism/secondary ASP from individuals with primary ASP/secondary alcoholism and, 2. to clarify, to the extent that such will be possible, through neuropsychological assessment the brain structures (lobes) associated with ASP and alcoholism.

Technical approach: The subject samples will be composed of six groups (1) alcoholics without ASP (ALC), (2) ASP without alcohol and/or drug problems (ASP), (3) primary alcoholics with secondary ASP (ALC+ASP), (4) primary ASP with secondary alcoholism (ASP+ALC), (5) a control group composed of patients with frontal lobe dysfunctions and without an antisocial personality disorder, and (6) a second control group composed of individuals who are antisocial but who do not have an antisocial personality disorder.

Progress: This is a new study. There is no reportable data.

Aug 95: One control group completed. Few patients have been enrolled in 2 other groups.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-06 Status: Ongoing

The Efficacy of Nebulized Dexamethasone in the Treatment of Acute Asthma

Start date: 21 Nov 94	Estimated completion date:
Principal Investigator: Dominic T. DiCiro, M.D.	Facility: DAH
Department/Service: Emergency Medicine	Associate Investigator(s): Marco Coppola, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 20 Nov 95 Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of nebulized albuterol with and without nebulized dexamethasone for the emergency department treatment of acute asthma in an adult population.

Technical Approach: Inhaled steroids have been used extensively for the adjunctive outpatient treatment of chronic asthma. However its efficacy in the treatment of acute asthma has not been well established. This investigation will examine if the addition of dexamethasone to nebulized albuterol treatments will provide quicker relief from the acute asthma episode. Other pertinent background information is outlined in protocol.

Progress: No report available as of this date. Annual review was due Nov 95.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-32 Status: Ongoing

Tamoxifen as Treatment for Idiopathic Gynecomastia

Start date: 2 Mar 95	Estimated completion date:
Principal Investigator: Vikram P. Zadoo, M.D.	Facility: DACH
Department/Service: Gen Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Mar of ea yr Review results: \_\_\_\_\_

Objective(s): To determine if tamoxifen is effective treatment for idiopathic gynecomastia.

Technical Approach: Active duty men between the ages of 20 to 40 with gynecomastia are eligible for inclusion into this study. Gynecomastia will be defined as a discrete, nonfibrotic, palpable breast enlargement centered around the periareolar complex. A thorough history, physical exam and pertinent laboratory data will exclude patients with non-idiopathic gynecomastia and patients who are without gynecomastia

Progress: No report available as of this date. Annual review due Mar 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-34 Status: Ongoing

Comparison of Outpatient Treatments for Pyelonephritis

Start date: 27 Feb 95	Estimated completion date:
Principal Investigator: Michael P. Applewhite, D.O.	Facility: DAH Emerg Medicine
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Feb of ea yr Review results: \_\_\_\_\_

Objective(s): To supply further evidence that outpatient management of acute pyelonephritis is a safe and effective way to treat a wide range of otherwise healthy men and women. Although many Emergency Departments are already treating patients with pyelonephritis on an outpatient basis, there remains controversy about the safety, efficacy and the population of patients for whom this is safe. This project would attempt to show the population in whom it is safe to treat as an outpatient, as well as safe choices and duration of antimicrobial therapy.

Technical Approach: To prove that outpatient management of healthy individuals with pyelonephritis is both safe and effective using a two week course of either oral plus IV antibiotics, or using oral antibiotics alone. Men and women presenting to the Emergency Department with signs and symptoms suggestive of pyelonephritis will be considered for the study.

Progress: No report available as of this date. Annual review due Feb 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-121 Status: Ongoing

Comparison of the Relationship Between Patient Height vs the Vertebral Column Length and the Level of Subarachnoid Sensory Blockade Produced Using 0.75% Bupivacaine

Start date: 11 Aug 95	Estimated completion date:
Principal Investigator: Bonnie Bequette, RN	Facility: DACH
Department/Service: Nursing Dept, DACH	Associate Investigator(s): Sandra Bruner, AN Kimberly Kurtz, AN Sheila Jones, AN Mark Evans, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Aug of ea yr Review results: \_\_\_\_\_

Objective(s): This study will answer th following research question: What is the correlation between patient height ersus the length of the vertebral column and the level of subarachnoid sensory blockade produced using 0.75% bupivicaine?

Technical Approach: The study will include 85 male or female adult inpatient volunteers.

Progress: Sep95: Have established inter-rater reliability among the investigators on the measurement of vertebral column length. In addition, have also estalished inter-rater reliability among the blinded observers on the measurement of dermatome levels. Currently preparing a research project inservice for the anesthesia staff. When the Committee for the Protection of Human Subjects at Univ of TX Houston Health Sci Cen has reviewed proposal, will commence research data collection in November.



# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-95-134 Status: Ongoing

Staged-Based Smoking Cessation Project

Start date: 11 Sep 95	Estimated completion date:
Principal Investigator: Beth Foley, MAJ, AN	Facility: DAH
Department/Service: Community Health Service	Associate Investigator(s): Patricia Gonzalves, LTC, AN Ken Hoffman, LTC, MC Andrea R. Krull, RN MPH
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Sep of ea yr Review results: \_\_\_\_\_

Objective(s): a. To devise a method to integrate inprocessing and health risk appraisal (HRA) systems on Army installations in order to: determine the prevalence of smoking among newly-arrived soldiers; analyze smoking prevalence by demographic categories and other health-related behaviors and risk factors and identify a cohort for longitudinal study of smoking behavior and smoking cessation. b. Among soldiers who are identified as smokers, to develop a method to assess intention to quit smoking, to study attempts to quit, and to determine long-term success rates for quitting. c. To evaluate the impact of an adaptive smoking cessation strategy on smoking rates in the identified population.

Technical Approach: Medical application; status; plan; analysis and further specifics are outlined in protocol.

Progress: No report available as of this date. Annual review due Sep 96.

# Detail Summary Sheet

Date: 1 Dec 95 Protocol Number: C-94-156 Status: Ongoing

## Cost Analysis and Patient Satisfaction of a Health Care Advisor Program

Start date: 24 Oct 94	Estimated completion date:
Principal Investigator: Linda Walton, AN	Facility: Fort Sill, OK
Department/Service: Reynolds Army Community Hospital	Associate Investigator(s): Donald Zamora, AN Kathy Choate, MSN Vicki Moon, MSN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Oct of ea yr Review results: \_\_\_\_\_

Objective(s): The purpose of this research study is to determine if a health care advisor program is cost effective while providing satisfactory patient care. This descriptive study will seek to answer the following research questions: (1) How does the implementation of a health care advisor program effect the cost of delivering outpatient health care to military beneficiaries? (2) To what extent are participants in the health care advisor program satisfied with the health care advice? (3) What is the volume and type of calls by time of day in a 24 hr period seven days a week of a health care advisor program?

Technical Approach: A non-experimental approach will be used to determine the effects of the implementation of a health care advisor program on the cost of delivering health care, the patient satisfaction with the health care program and the number and mix of health care advisors needed to meet the needs of the military community at Fort Sill OK. A descriptive study will be used to identify the level of satisfaction of the program by the participants. The overall cost avoidance of the health care advisor program will be described. This study will also seek to describe the staffing patterns to fulfill the communities need for health care advisor access.

Progress: Dec 95: No activity during this fiscal year. Grant extended to 30 Sep 95.

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